THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

MAYOR AND CITY COUNCIL OF BALTIMORE, on behalf of itself and all other similarly situated,

Plaintiff

v.

BIOGEN, INC.,

Defendant.

CLASS ACTION COMPLAINT

JURY TRIAL DEMAND

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Plaintiff, the Mayor and City Council of Baltimore ("Plaintiff" or "City of Baltimore") is a municipality that provides healthcare benefits to its employees, retirees, and their beneficiaries. Plaintiff, on behalf of itself and all other similarly situated health plans, based upon personal knowledge, the investigation of counsel, and upon information and belief, alleges as follows against defendant Biogen, Inc.:

I. NATURE OF THE ACTION

1. This civil antitrust action seeks damages and other relief arising out of defendant Biogen, Inc.'s unlawful scheme to impair competition from generic versions of its brand-name prescription drug Tecfidera. Tecfidera is used to treat multiple sclerosis ("MS").

2. The Food and Drug Administration ("FDA") approved Tecfidera in 2013, and it quickly reached blockbuster status, achieving $3.5 billion in U.S. sales by 2015 and remaining in the range of $3.3 to $3.8 billion annually through 2020.

3. These sales reflected Tecfidera's extremely high sales price, which rose to nearly $90,000 per patient per year. Biogen's manufacturing costs were less than $300 per patient per year—it sold Tecfidera at 300 times its costs. Biogen was able to reap these monopoly profits because it had a patent on Tecfidera.

4. But that patent was very weak. Beginning in 2017—as soon as legally permissible—numerous generic-drug manufacturers began challenging the validity of the Tecfidera patent. Biogen knew that once it lost those patent lawsuits its Tecfidera sales and profits would fall off the "patent cliff." Generic versions would quickly take 90% or more of the unit sales and would be sold at a small fraction of Biogen's price. This competition would save billions of dollars for Plaintiff and other purchasers of Tecfidera.

5. To forestall this competition and the consequent loss of its sales, Biogen crafted a market-switch strategy. Biogen developed a "next generation" version of Tecfidera, called

Vumerity. Vumerity and Tecfidera create the same active drug substance—monomethyl fumarate—in the body. They each deliver the same bioequivalent exposure to monomethyl fumarate and therefore have the same effectiveness and safety profile. In fact, Biogen got expedited FDA approval of Vumerity by proving that it was bioequivalent to Tecfidera, i.e., that its active ingredient is present in the patient's blood to the same extent and for the same amount of time.

6. Vumerity was different from Tecfidera not in a medically important way, but in an *economically* important way. When filling a prescription written for Vumerity, pharmacists could not automatically substitute generic Tecfidera. So Biogen's plan was to orchestrate a market switch—to get doctors to switch their prescribing from Tecfidera to Vumerity before the generic versions of Tecfidera were available in the marketplace. Biogen would tell doctors and patients that Vumerity was "new and improved" even though in fact it had no medically significant advantages over Tecfidera. If doctors wrote prescriptions for Vumerity rather than Tecfidera, pharmacists could not dispense generic Tecfidera for those prescriptions.

7. Timing was essential to Biogen's scheme. Biogen would need to accomplish the market switch before generic Tecfidera became available. It is well known in the industry that a switch to a follow-on product like Vumerity—one with no important medical improvements—would succeed only if the switch occurred before generic versions of the original product became available.

8. Biogen ran into three problems on the timing of its planned market switch. Biogen's launch of Vumerity was complicated by the onset of the coronavirus disease 2019 ("COVID-19") pandemic, which prevented Biogen's sales force from marketing Vumerity to doctors in-person. And Biogen had planned to get more time to make the market switch by

settling the Tecfidera patent lawsuits with an agreement by the generic challengers to delay their entry into the market. That plan went awry because Biogen's patent was so weak that the generic manufacturers refused to settle on those terms. Then when the courts hearing the patent cases ruled that the Tecfidera patent was invalid, the generic manufacturers entered the market immediately, without waiting to see if the invalidity ruling would be upheld on appeal (as it eventually was). This cut 18 months off the time that Biogen thought it would have to make the market switch from Tecfidera to Vumerity.

9. The cumulative effect of Biogen's timing problems was stark. Instead of having converted nearly 100% of Tecfidera sales to Vumerity before the Tecfidera generics entered the market, Biogen had converted about 1% of them.

10. So Biogen resorted to using unlawful, anticompetitive agreements to block the distribution of generic Tecfidera while it scrambled to switch the market. Biogen entered into unlawful restraints of trade with each of the nation's three largest pharmacy benefit managers—Caremark Rx, LLC, OptumRx, Inc., and Express Scripts, Inc. Collectively, these three Pharmacy Benefit Managers ("PBMs") control the pharmacy benefits for 80% of Americans. Biogen paid the PBMs to manipulate the placement of generic Tecfidera on their formularies—the lists that identify which drugs are covered and establish the applicable patient copayments and coinsurance.

11. Biogen paid each of the three PBMs (and others) to refrain from advantaging generic Tecfidera over branded Tecfidera and Vumerity on their formularies. Biogen labeled these payments as "rebates" or "fees." In reality they were kickbacks to the PBMs for helping to insulate Tecfidera and Vumerity from lower-priced generic competition.

12. While the PBMs passed some of the rebates (none of the fees) on to some of their customers, the rebates were not legitimate and honest ways for Biogen to compete with generic Tecfidera on price. Seven months after entering the market, generic Tecfidera was selling for greater than a 90% discount off the list price of branded Tecfidera. In contrast, Biogen's average rebates and fees on branded Tecfidera were less than 19% off the list price. Biogen's rebates and fees were payments *to the PBMs* in exchange for excluding the generics, not price reductions to the health plans that, even if fully passed on to them, would have produced savings anywhere near what the generics offered.

13. These bought-and-paid-for manipulations substantially muted the competition from generic Tecfidera. That period of impaired competition, in turn, gave Biogen the time it needed to switch a large portion of the market from Tecfidera to Vumerity. That market switch significantly and permanently impaired generic competition, and the harms from it continue today.

14. Piling injury upon injury, Biogen's requirement that the PBMs not advantage generic Tecfidera on the formularies caused some of them to designate generic Tecfidera as a "specialty drug." But nothing about generic Tecfidera required special handling—it is a shelf-stable pharmaceutical dispensed as a pill. Nor did it carry a high acquisition cost which sometimes results in a product being designated a "specialty drug." This was not a legitimate designation for generic Tecfidera.

15. The purpose and effect of Biogen's causing that designation was to require insured patients to incur a very high copayment or coinsurance for generic Tecfidera, muting their incentive to demand or accept the generic. Another purpose and effect was to require that the falsely designated generic be dispensed only through a small number of "specialty

pharmacies," shielding those pharmacies from price competition from all other pharmacies. Notably, Biogen's co-conspirator PBMs owned specialty pharmacies.

16. Biogen knew and intended that causing generic Tecfidera to be distributed through this small set of specialty pharmacies would substantially depress the sales of generic Tecfidera. It kept generic Tecfidera's price to health plans and other purchasers astronomically high. The PBM-affiliated specialty pharmacies bought generic Tecfidera from the manufacturers for as little as $180 for a 30-day supply; they sold it to the health plans and their insureds for as much as $3,857 for a 30-day supply. That is more than a 2,000% markup.

17. Biogen's conduct had the intended effect. With unimpaired generic competition, within 10 months of generic availability pharmacies would have been dispensing about 2.2 million units of generic Tecfidera every month; instead they were dispensing about a third of that amount. Correspondingly, pharmacies would have been dispensing fewer than 300,000 units of branded Tecfidera and Vumerity (combined) every month; instead they were dispensing more than five times that amount. Even today—four years after generic entry—Biogen's unlawful conduct has suppressed generic Tecfidera sales far below the competitive level, while artificially inflating the sales of high-priced Tecfidera/Vumerity.

18. When making the payoffs to the PBMs, Biogen knew that Plaintiff and other health plans hired the PBMs to negotiate with Biogen and other drug manufacturers on their behalf. Biogen knew that health plans trusted the PBMs to make formulary placement decisions to help them reduce prescription drug costs. Biogen paid the PBMs to instead impair the generic competition that it was the PBMs' proper, lawful role and obligation to promote.

19. Biogen also knew that each of the three PBMs had recently established a separate, affiliated "rebate aggregator"—an entity that negotiates contracts, including for fees and rebates,

with drug manufacturers. When making the payoffs at issue here, Biogen knew that one of the functions of the PBMs' affiliated rebate aggregators was to hide the rebates and fees from the PBMs' health-plan clients. A former OptumRx executive who helped establish its affiliated rebate aggregator explained that "[t]he intention of the [rebate aggregator] is to create a fee structure that can be retained and not passed on to a client."

20. All of this occurred at the expense of MS patients and those who provide prescription drug coverage such as Plaintiff, which were forced to continue paying supracompetitive prices for Vumerity, Tecfidera, and its generic equivalents. Biogen denied to purchasers the massive cost savings that would and should have resulted from unimpaired generic competition.

21. These supracompetitive prices place a notable financial strain on health plans, because they directly shoulder the burden of high-cost prescription drugs. Smaller businesses feel this strain most acutely; the high cost of even a single specialty medication can represent a significant proportion of the overall health-benefit costs.

22. Together with its PBM Co-Conspirators, Biogen has unlawfully (1) restrained, suppressed, and eliminated competition in the market for Vumerity, Tecfidera, and their generic equivalents; (2) maintained monopoly and supracompetitive prices for those drug products; and (3) prevented Plaintiff from purchasing the drugs in a competitive market, robbing them of billions of dollars in the aggregate.

II. PARTIES AND BIOGEN'S CO-CONSPIRATORS

A. Plaintiff

23. Plaintiff, the Mayor and City Council of Baltimore ("Plaintiff" or "City of Baltimore") is a municipality located in Baltimore, Maryland. Plaintiff provides health benefits to eligible employees, retirees, and their beneficiaries. Plaintiff provides self-insured prescription

drug coverage, and it purchases, pays and/or provides reimbursement for some or all of the purchase price of prescription drugs, including Vumerity, Tecfidera, or its generic equivalents.

24. During the Class Period, Plaintiff indirectly purchased substantial amounts of Tecfidera or Vumerity from Biogen in, among other jurisdictions, Florida and Maryland, for the personal use of its members and beneficiaries, other than for resale. Plaintiff and other Class members also purchased substantial amounts of AB-rated generic Tecfidera directly from others, including Biogen's Co-Conspirator specialty pharmacies, for personal use by their members and beneficiaries. Plaintiff and other Class members paid more for Vumerity, Tecfidera, or its generic equivalents than they would have absent Biogen's unlawful anticompetitive conduct and were injured as a result. If generic alternatives to Tecfidera had been competitively available during the Class Period, Plaintiff and the other Class members would have purchased more of the less expensive generic alternatives rather than branded Tecfidera or Vumerity, or would have paid less for generic Tecfidera.

B. Defendant

25. Defendant Biogen Inc. is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 225 Binney Street, Cambridge, Massachusetts. Biogen is a manufacturer and seller of branded prescription pharmaceuticals, including Tecfidera and Vumerity. It regularly conducts business throughout the United States, including in this judicial district.

26. All of Biogen's actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Biogen's various officers, agents, employees, or other representatives while actively engaged in the management of its affairs (or that of its predecessors-in-interest) within the course and scope of

their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Biogen.

C. Co-Conspirators

27. Co-Conspirator CVS Health Corporation ("CVS Health") is a Delaware corporation with its principal place of business located in Woonsocket, Rhode Island. It is a healthcare behemoth that owns and controls, among other entities, a major health insurer, one of the top three PBMs, a specialty pharmacy, a mail-order pharmacy, and more than 9,000 retail pharmacy locations.

28. CVS Health owns, directly or indirectly, Caremark Rx, LLC, the PBM that also owns Caremark, LLC, which also provides PBM services; CVS Specialty Pharmacy, the specialty pharmacy; and CVS Caremark Mail Service, the mail-order pharmacy. Each of the foregoing CVS Health-affiliated entities has its principal place of business at the same location as CVS Health and is a Co-Conspirator with Biogen in the unlawful conduct alleged below. Co-Conspirators CVS Health, Caremark Rx, LLC, Caremark, LLC, CVS Specialty Pharmacy, and CVS Caremark Mail Service are collectively referred to herein as "CVS Caremark."

29. Co-Conspirator Evernorth Health, Inc. ("Evernorth"), formerly known as Express Scripts Holding Company, is a Delaware corporation with its principal place of business in St. Louis, Missouri. It is a healthcare behemoth that owns and controls, among other entities, a major health insurer, one of the top three PBMs, a specialty pharmacy, and a mail-order pharmacy. In 2018, Express Scripts Holding Company merged with Cigna Corporation ("Cigna") in a $67 billion deal to consolidate their businesses as a major health insurer, PBM and mail-order pharmacy.

30. Evernorth owns, directly or indirectly, Express Scripts, Inc., the PBM; Accredo Health Group, Inc. d/b/a Accredo Specialty Pharmacy ("Accredo"), the specialty pharmacy; and Express Scripts Pharmacy, the mail-order pharmacy. Express Scripts, Inc., and Express Scripts Pharmacy each has its principal place of business at the same location as Evernorth. Accredo's principal place of business is located in Memphis, Tennessee. Each of the foregoing Evernorth-affiliated entities is a Co-Conspirator with Biogen in the unlawful conduct alleged below. Co-Conspirators Evernorth, Express Scripts, Inc., Accredo, and Express Scripts Pharmacy are collectively referred to herein as "Express Scripts" or "ESI."

31. Co-Conspirator UnitedHealth Group, Inc. ("UHG") is a Delaware corporation with its principal place of business in Minnetonka, Minnesota. It is a healthcare behemoth that owns and controls, among other entities, a major health insurer, one of the top three PBMs, a specialty pharmacy, and a mail-order pharmacy.

32. UHG owns, directly or indirectly, OptumRx, Inc., the PBM which also provides specialty pharmacy and mail order pharmacy services through its specialty pharmacy, Optum Specialty Pharmacy, and its mail order pharmacy, Optum Mail Service Pharmacy. OptumRx, Inc. has its principal place of business in Irvine, California. Each of the foregoing UHG-affiliated entities is a Co-Conspirator with Biogen in the unlawful conduct alleged below. UHG, OptumRx, Inc., Optum Specialty Pharmacy, and Optum Mail Service Pharmacy are collectively referred to herein as "OptumRx."

33. All of the Co-Conspirators are collectively referred to herein as "PBMs," and their wrongful actions described in this Complaint are part of, and in furtherance of, the unlawful restraints of trade alleged herein, and were authorized, ordered, and/or undertaken by the Co-Conspirators' various officers, agents, employees, or other representatives while actively

engaged in the management of the Co-Conspirators' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the Co-Conspirators.

III. JURISDICTION AND VENUE

34. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 and at least one member of the putative class is a citizen of a state different from that of Biogen.

35. This Court also has jurisdiction over this matter pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 in that Plaintiff brings claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Biogen's violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S. C. § 1 and 2, and under Section 4(a) of the Clayton Act, 15 U.S.C. § 15(a), for damages and other relief to remedy Biogen's violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S. C. § 1 and 2 and of Section 2(c) of the Robinson-Patman Act, 15 U.S.C. § 13(c). The Court has supplemental jurisdiction over Plaintiff's pendent state law claims pursuant to 28 U.S.C. § 1367.

36. This Court has personal jurisdiction over Biogen under Section 12 of the Clayton Act, 15 U.S.C. § 22. The Court also has personal jurisdiction over Biogen under the Illinois long-arm statute, 735 ILCS 5/2-209(a)(7). The claims of Class members arise out of or relate to Biogen's conduct in this district. Certain class members made relevant purchases here; Biogen employs salespeople based in this district to market Biogen's products, including convincing doctors here to prescribe Tecfidera and Vumerity; Biogen advertises Tecfidera and Vumerity to people living in this district, including running a national television advertising campaign for Tecfidera that targeted and reached residents of this district; and Biogen's unlawful conduct

caused PBMs to disadvantage generic Tecfidera on formularies covering residents of this district and caused health plans and consumers in this district and elsewhere to incur overcharges on their purchases covered by those formularies.

37. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22, and under 28 U.S.C. §1391(b) and (c), because Biogen transacts business within this district and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district.

IV. THE IMPORTANCE OF GENERIC DRUGS

A. The High Price of Branded Drugs

38. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit to get or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the product's price plays an appropriate role in the person's choice of products and, consequently, the manufacturers have an appropriate incentive to lower their prices.

39. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Tecfidera and Vumerity, to patients without a prescription written by a doctor. The prohibition on dispensing the drug without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the drug, but the patient's doctor chooses which drug the patient will buy.

40. Biogen and other brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the drugs. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

41. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand—a measure of the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power.

42. The result of the market imperfections and marketing practices described above is that brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals.

B. The Regulatory Structure that Promotes Generic Drugs

43. The relevant drug-regulation framework is established by the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 ("Hatch-Waxman Amendments"). Under FDCA, branded drug manufacturers that wish to sell a new drug product must obtain approval from the FDA by filing a New Drug Application ("NDA"). 21 U.S.C. § 355(b). The NDA must include, among other things, a statement of the drug's components, active ingredients, scientific data showing that the drug is safe and effective, patent information, and

proposed labeling describing the methods by which a drug may be used and administered. 21 U.S.C. §§ 355(a), (b).

44. Upon FDA approval of the NDA, the FDA lists any patents that the manufacturer asserts could reasonably be enforced against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the listed patents expire. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, because it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness.

45. The Hatch-Waxman Amendments speed generics onto the market. The Amendments' fundamental premise is that many branded prescription drugs have market power and that only competition from generic drugs can bring competitive prices. The evidence on which Congress relied showed that, even after brand-drug patents had expired, competition among branded drugs was insufficient to deliver competitive prices. Only competition from generic drugs could drive prices to the competitive level.

46. The Amendments speed generics onto the market several ways. The Amendments simplify the regulatory hurdles for generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. Instead, generic manufacturers can file an Abbreviated New Drug Application ("ANDA"), which relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA. The generic manufacturer need only show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent

(together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to their brand-name counterpart an "AB" rating.

47. The FDCA and Hatch-Waxman Amendments operate on the basis that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent. Bioequivalence demonstrates that the proposed generic drug's active ingredient would be present in the patient's blood to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B). So a generic drug that receives an AB rating from the FDA may safely be substituted for the brand drug.

48. In addition to easing FDA approval for generic drugs, the Hatch-Waxman Amendments also eased their pathway through litigation over the brand manufacturer's patents. A generic manufacturer that certifies that its product will not infringe the brand's patents may be able to litigate the patents' validity and applicability without subjecting itself to patent-infringement damages if it were to lose the litigation. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). And Congress encouraged manufacturers to challenge brand-drug patents, providing a valuable period of generic-drug exclusivity—essentially, a financial bounty often worth hundreds of millions of dollars—for the first manufacturer that initiates a challenge to such a patent. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D).

49. State legislation has supplemented Congress's efforts to speed generics onto the market. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise).

50. Like the Hatch-Waxman Amendments, these state drug-product selection laws are founded on the premise that, before generic entry, branded drugs typically have market power. If they did not have market power, there would be little or no need for state laws that permit or require the pharmacist to substitute a generic.

51. The combined federal and state efforts to promote generic competition—when not undermined by manufacturers' or others' anticompetitive conduct—have been largely successful. In 1983, before the Hatch-Waxman Amendments and state generic-substitution laws, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. By 2013, generic drugs accounted for 86% of all prescriptions dispensed. Today, generics are dispensed 95% of the time when a generic version is available.

C. The Competitive Effects of AB-rated Generic Competition

52. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective as their brand-name counterparts. The only material difference between generic drugs and their corresponding brand-name versions is their price.

53. Generic versions of a corresponding branded drug product are commodities that cannot be differentiated, so the primary basis for generic competition is price. Typically, generics are at least 25% less expensive than their brand-name counterparts when there is a single generic competitor, and this discount typically increases to 80% (or more) when multiple generic competitors are on the market for a given brand. Consequently, the launch of a generic drug usually results in significant cost savings for all drug purchasers.

54. Once a generic equivalent hits the market, the generic quickly takes sales from the corresponding branded drug, often capturing 90% or more of the market within the first six

months, and 95% or more during the first 12 months. As a result, brand drug companies, including Biogen, view competition from generic drugs as a grave threat to their bottom lines.

55. By impairing generic competition, the brand manufacturer can continue to profitably charge supracompetitive prices. Brand manufacturers, including Biogen, are well aware of generics' rapid erosion of their brand sales. Brand manufacturers therefore try to extend their monopoly for as long as possible by impairing generic competition, sometimes resorting to any means possible—including illegal means.

V. THE PROMISE AND PERIL OF PBMS

56. PBMs manage prescription drug benefits on behalf of their clients, which include health insurance companies, self-funded health plans, large companies, and governmental entities.

A. The Promise

57. One of the principal roles for PBMs is to create and maintain a drug formulary for the PBM's clients. A formulary is a list of prescription drugs for which the health plan will reimburse pharmacies on behalf of the plan's members. The formulary also describes the copayment or coinsurance for which the covered patient is responsible. A proper formulary will almost always provide a lower copayment or coinsurance for generic drugs as compared to their brand-drug counterparts. This incentivizes the patients to demand or accept the generic drug.

58. The purpose behind a proper drug formulary is to provide quality care using the most cost-effective options. If a drug is not included on a formulary, the health plan generally will not cover the cost of the drug. Thus, if a doctor prescribes a drug that is not on the formulary, the patient will be required to pay the entire cost of the drug out-of-pocket.

59. Prominent among PBMs' proper roles is to aggressively promote the use of generic drugs whenever possible. As noted above, generic drugs can quickly deliver discounts of 90% or more off the price of the branded drug.

60. A properly acting PBM has several powerful tools available to promote insureds' use of generic drugs when they are available. Important among these is placing the generic on the most advantageous tier on the formulary.

61. When rival drugs are available to treat the same condition, a PBM's formulary may prefer certain of those drugs over other "non-preferred" drugs. When PBMs are not bribed to do otherwise, their formularies use a "tier" system to promote effective but less costly drug alternatives.

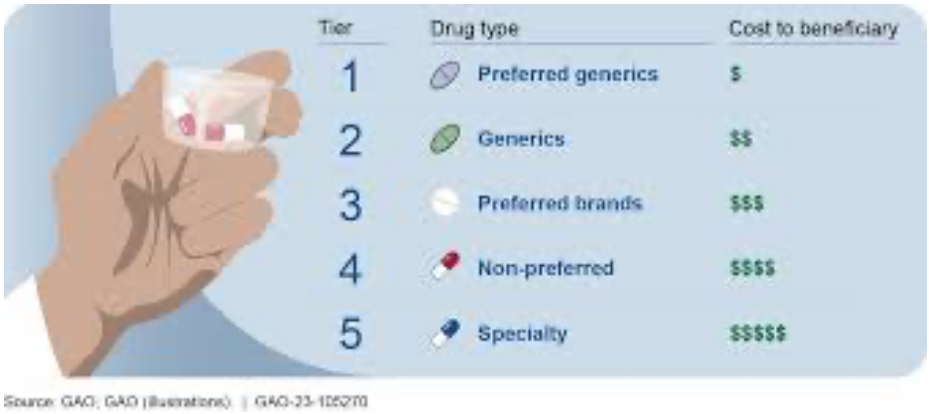
62. PBMs place drugs into different tiers on their formularies, with five tiers being typical. Generally, drugs in a lower-numbered tier cost beneficiaries less than drugs in higher-numbered tiers, with generic drugs on the lowest-numbered tier and brand-name and specialty drugs on a higher-numbered tier. For example, tier 1 may include most generic prescription drugs, while tier 5 may include specialty drugs, which include high-cost prescription drugs with the highest cost-sharing.

63. Formularies typically provide for lower patient cost-sharing—the amount the insured must pay through co-payments or coinsurance—for drugs on the lowest-numbered (i.e., the best) tier. Properly acting PBMs almost always promote generic drugs by placing them on Tier 1.

64. For both generic and brand-name drugs, PBMs may offer preferred and non-preferred tiers. Drugs in preferred tiers are generally more cost-effective than drugs in non-

preferred tiers. Preferred brand-name and generic drugs also generally have lower cost-sharing than non- preferred brand-name and generic drugs.

65. Cost sharing can vary substantially by tier. For example, among those in plans with four tiers, average cost-sharing ranged from $12 copayment or 20% coinsurance for first tier/preferred drugs to a $124 copayment or 32% coinsurance for fourth tier drugs. Such tiering promotes the use of lower cost drugs that are more accessible, such as generics, on the lower tiers compared to the more costly nonpreferred brand drugs typically included on the higher tiers.



66. In addition to formulary tiers, PBMs can promote generic drug use by implementing drug utilization management tools. These tools promote generic drugs over brands by imposing policies on prior authorization (which involves a review and sign-off by a PBM-employed health care provider before a patient can obtain a prescribed drug), step therapy (which requires a patient to try a preferred option on the formulary before the insurer will cover the originally-prescribed drug), and quantity limits (such as restricting the number of doses a patient can receive for a particular condition).

67. Promoting generic drugs instead of brands is a principal way for PBMs to control drug costs for health plans and patients. In 2020 alone, the use of generic medicines saved the healthcare system an estimated $313 billion. On average, patients pay only $6.97 out of pocket

for generic medicines, with over 90% of generic prescriptions costing patients less than $20 in 2020.

68. PBMs also create pharmacy networks through which the insureds get their covered prescriptions filled. This typically includes mail order pharmacies in addition to "brick and mortar" pharmacies.

69. In sum, through their control of formularies and pharmacy networks, PBMs have a prominent role in determining which drugs will be accessible to patients and at what cost.

B. The Peril

70. Over the past 20 years, the PBM marketplace has become increasingly concentrated. In 2004, the top three PBMs served a combined 190 million people and managed 52% of prescription drug claims. Today, the three PBMs manage about 80% of prescription drug claims, for about 270 million people. With some overlap among them the top three PBMs are: CVS Caremark, which manages the claims of 103 million people; ESI, which manages the claims of more than 100 million people; and OptumRx, which manages the claims of over 66 million people.

71. The high concentration of these massive companies is further exacerbated by the concentration in common ownership of each. The ownership of each PBM parent organization (UHG, CVS Health Corporation, and Cigna) includes the same six companies among their top 10 Institutional Holders. Together, these six shareholders own 27% to 32% of each PBM parent organization, owning nearly one-third of $819.5 billion of the companies' combined market value. This common ownership reduces competition by diminishing incentives to compete and increasing the ability to share competitively sensitive information.

72. Each of the three PBMs has become vertically integrated with various entities along the pharmaceutical supply chain, giving them even greater power and control over the distribution and pricing of drugs. Each PBM's vertical integration gives it near complete control of the pricing, dispensing, and reimbursement system for all prescription drugs for its covered lives. This control permits the PBM to work with drug manufacturers to drive up drug prices and foreclose patients' access to competitors' less costly drugs. The result is increased profits for the PBMs and brand manufacturers, and higher drug prices for consumers and health plans.

73. This graphic depicts each PBM's vertical integration with midstream distributors, including retail, mail order, and specialty pharmacies. Each is also vertically integrated with a health insurer that controls drug coverage for hundreds of millions of Americans.

Parent/Owner	CVS Health Corporation	The Cigna Group	UnitedHealth Group Inc.
Drug Private Labeler	Cordavis Limited	Quallent Pharmaceuticals	NUVAILA
Health Care Provider	MinuteClinic, Signify Health	Evernorth Care Group	Optum Health
Pharmacy Benefit Manager	CVS caremark 34%	EXPRESS SCRIPTS 23%	Optum Rx 22%
"PBM GPO"/ Rebate Aggregator	Zinc Health Services	Ascent Health Services	Emisar Pharma Services
Pharmacy - Retail	CVS Pharmacy		
Pharmacy - Mail Order	CVS Caremark Mail Service Pharmacy	Express Scripts Pharmacy	Optum Rx Mail Service Pharmacy
Pharmacy - Specialty	CVS Specialty Pharmacy	Accredo	Optum Specialty Pharmacy
Health Insurer	Aetna	Cigna Healthcare	UnitedHealthcare

74. Especially relevant here are the "specialty pharmacies" that the PBMs sometimes include in their pharmacy networks. A specialty pharmacy primarily dispenses "specialty drugs" and may be a brick-and-mortar pharmacy or a mail order pharmacy. The vast majority are mail order pharmacies. Historically, specialty drugs were characterized by their need for special handling and administration.

75. Today, however, PBMs exercise unregulated discretion in classifying drugs as specialty medications. Some PBMs designate a drug as specialty based solely on its high cost. When a PBM vertically integrates with a specialty pharmacy, it has an increased ability to steer patients to its own in-house specialty pharmacy and toward more expensive drugs—in exchange for payments from brand manufacturers.

76. The prescriptions having been steered into a limited-distribution channel—shielded from the retail-level competition provided by the nation's tens of thousands of retail pharmacies—the PBM-affiliated specialty pharmacies can and do charge outrageous prices to patients and health plans for those drugs. It is not unusual for those specialty pharmacies to charge prices 20-40 times higher than their acquisition costs.

77. Specialty drugs account for a growing share of pharmacy dispensing revenue (about 40-50%) but only a small fraction of total prescription volume (about 2%). A PBM's designating a product as a specialty drug may trigger provisions in its contract with a health plan that require the insureds to fill the prescription only at the PBM's affiliated specialty pharmacy. The specialty pharmacies affiliated with one of the three PBMs account for nearly 70% of all specialty-drug revenue.

78. In 2023, CVS Specialty, owned by CVS Health, earned $73.3 billion in revenues from specialty drugs, which accounted for 30% of all prescription revenues from specialty drugs.

Accredo, owned by Cigna/Evernorth, earned $59.5 billion in revenues from specialty drugs, which accounted for 24% of all prescription revenues from specialty drugs. And Optum Specialty Pharmacy, owned by UnitedHealth Group, earned $32.3 billion in revenues from specialty drugs, which accounted for 13% of all prescription revenues from specialty drugs. Overall, mail order pharmacies accounted for more than three-quarters of the industry's $243 billion in total prescription revenues from specialty drugs.

79. Other economic trends in the PBM marketplace confirm that the consolidation and vertical integration in the PBM industry has warped PBMs' incentives and set the stage for brand-drug manufacturers to cause economic harm to drug purchasers.

80. For example, the PBMs have begun accepting rebates and "fees" from brand manufacturers in exchange for skewing their formularies to favor higher-priced brand drugs over low-cost generic drugs. The brand manufacturers and PBMs win; patients and health plans lose. Similarly, by prioritizing specialty and branded drugs over generics, PBMs can raise drug prices and push consumers toward more expensive options, decreasing the use and availability of lower-cost generics.

81. The PBMs and brand manufacturers, including Biogen, have created a "hide-the-ball" system where the consideration that the manufacturer pays to the PBMs (and does not share with payors) is labeled and relabeled. As more health plans required PBMs to pass a majority of the manufacturer "rebates" through to them, PBMs started renaming the payments in order to keep a larger portion of them. Payments once known as "rebates" are now called administrative fees, volume discounts, service fees, data usage fees, inflation fees, or other industry jargon terms designed to obfuscate and distract from the substantial sums being secretly exchanged.

82. The PBMs perform no services for these unearned fees or payments. In return for these fees paid by brand manufacturers, including Biogen, the only thing the PBMs do is disadvantage and suppress lower cost drugs.

83. PBMs have also begun using "rebate aggregators" to negotiate the payments they will receive from the brand manufacturers. Using rebate aggregators allows the PBMs to hide the payments from regulators and the health plans. PBMs have recently doubled the amount of fees they get from drug manufacturers, from $3.8 billion in 2018 to $7.6 billion in 2022.

84. The PBMs carefully guard the revenue streams they receive from their rebate aggregator activities, hiding them in complex contractual relationships and not reporting them separately in their quarterly SEC filings.

85. Further reducing transparency, and making oversight more difficult, two of the three PBMs have located their affiliated aggregators offshore. Express Scripts located its aggregator, Ascent Health, in Switzerland. OptumRx located its aggregator, Emisar Pharma Services, in Ireland.

86. A recent study by the Pew Charitable Trust estimated that, between 2012 and 2016, the amount of administrative and other fees that the PBMs requested and received from the brand manufacturers tripled, reaching more than $16 billion. That growth in "fees" has continued to accelerate since 2016.

87. In short, health plans cannot defeat the PBMs' accepting payments from brand manufacturers. Health plans may choose which pharmacy networks and drug formularies to use, but information asymmetries hinder their ability to make fully informed decisions. So most health plans accept the standard formularies that the PBMs offer or otherwise defer to their

formulary recommendations. Indeed, health plans hire PBMs for their expertise, including in formulary management.

88. From 2016 to 2023, the total revenues of the CVS healthcare conglomerate rose from $177.5 billion in 2016 to $357.8 billion. Those of the Cigna healthcare conglomerate rose from $39.7 billion to $195.3 billion, and those of the United Healthcare conglomerate rose from $184.8 billion to $371.6 billion. They also expanded their operating profits; the three conglomerates' combined profits rose from $31.4 billion in 2016 to more than $58.4 billion in 2023.

89. PBMs began as a partial solution to the problem of brand-drug manufacturers' market power. Formularies and other competitive tools were capable of generating some competition among branded drugs, and of promoting generic drugs after brand-drug patents expired. But once these commercial behemoths achieved dominance up and down the pharmacy distribution chain, they have proved only too willing to wield that dominance at the behest of brand-drug manufacturers. In exchange for payments from the brand-drug manufacturers, the PBMs have thwarted the generic competition that is their legitimate role to promote.

VI. BRAND MANUFACTURERS' ANTICOMPETITIVE TACTICS

90. Over the years, brand manufacturers have developed an arsenal of anticompetitive tactics to impair generic competition. Two are most relevant here.

A. Market Switches

91. One tactic to impair generic competition is to prevent the generic drug from being AB-rated to the brand drug, thereby preventing automatic generic substitution. The AB-rating requirement for generic drugs is designed to ensure therapeutic equivalence to the reference (brand) product. It is concerned only with safety and efficacy, not with effects on competition.

92. Regulations permit brand manufacturers to seek FDA approval to modify the dosage form and strength of their existing products. An unscrupulous brand manufacturer that anticipates the onset of generic competition to its drug can modify the dosage form, strength, or some other characteristic of its product from, say, A to A_1, for the purpose of preventing the anticipated generic product from being AB rated to the new brand product. Before the generic manufacturer receives FDA approval for the generic version of A and enters the market, the brand manufacturer can get approval for A_1 and cannibalize the sales of A—use its massive sales force to get doctors to switch their prescriptions from A to A_1.

93. Thus, before the generic of A enters the market the brand manufacturer will have: (a) ensured that the generic product cannot be AB rated to, and substitutable for, A_1; and (b) switched the prescription base from A to A_1. Consequently, when the generic finally gets FDA approval to enter the market, it will garner substantially reduced sales because it is not substitutable for the new brand product to which the brand manufacturer has switched the prescription base.

94. The timing of the switch is critical. It is well known in the pharmaceutical industry that if generic versions of the original brand product enter the market before the branded follow-on product, the latter will make very few sales unless it offers substantial, demonstrable medical benefits to consumers. For example, one brand manufacturer estimated that it would make ten times more sales of its branded follow-on product if it beat generic versions of the original product onto the market. In a detailed inquiry into the pharmaceutical industry, the European Commission concluded that "it is of utmost importance for the originator company to bring the follow-on product on the market before the first product effectively loses exclusivity." European Commission, Final Report, p. 356 (8 July 2009), http://www.europa-

nu.nl/id/vi6wcj7amsx3/pharmaceutical_sector_inquiry_fianl?start-006-00c=10. Industry analysts in the United States have reached the same conclusion, warning brand manufacturers that it is essential that they switch patients to the new formulation before the generic enters.

95. It is equally well known that, after a market switch, doctors are unlikely to prescribe the original product—in this case, Tecfidera. Having switched their prescribing habits from the original to the reformulated product—and having switched specific patients' medications from the original to a reformulated product—most doctors will not switch their prescribing habits or their patients back to the original product after the generic is available. In economic terms, switching costs (e.g., the need for another visit to the doctor for a new prescription) impair a move back to the original product. And pharmaceuticals are "experience" goods that consumers and physicians are hesitant to change if they are working.

96. Brand manufacturers know that, if they successfully cannibalize the original product's sales before the generics enter the market, the generics are not likely to *ever* compete effectively for those switched prescriptions. Automatic substitution at the pharmacy counter is a generic product's only commercially viable means of competing. Once the brand's patents are no longer effective, *no one*—neither the brand manufacturer nor any generic manufacturers—can profitably market the product on a basis other than price. Costs incurred to encourage a doctor to write a prescription for the firm's own product would be squandered because the pharmacist can fill the prescription with a competitor's AB-rated product.

97. And this is a good thing. If a manufacturer could profitably market the product to doctors on a basis other than price, this would merely replicate the price-disconnect failure in these markets. The price disconnect is the problem, and AB-rated substitution at the pharmacy

counter is the solution. The generic-substitution regime is *designed* to render unprofitable active marketing of the product to doctors.

98. Once the market switch is done, pharmacists are unable to dispense the generic drug through the efficient mechanism of automatic substitution because the dosage form and/or dosage amount is different. Thus, in most instances, the generic's opportunity to compete for those sales is gone forever.

B. Kickbacks to PBMs

99. The recent changes in the PBM industry have set the stage for brand-drug manufacturers to enlist PBMs in impairing rather than promoting generic competition. The vertical integration and market concentration have made it profitable for the PBMs to accept kickbacks from the brand manufacturers to impair generic competition.

100. The basic economics demonstrate why.

101. The brand manufacturer and the PBMs have a collective economic interest in impairing generic competition. If they work together to hinder generic competition, they can keep the profit margins on all the unit sales high and split the resulting excess profits among themselves. They can keep the enormous savings that generic competition would have delivered to drug purchasers. The following series of pie charts demonstrates the brand manufacturer's and PBMs' collective interest in reducing generic competition.

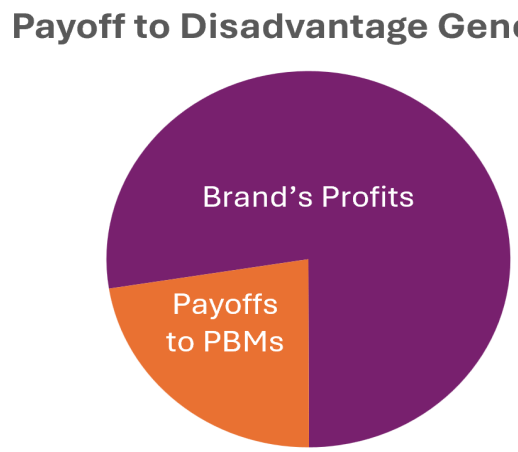
102. A brand manufacturer in the marketplace without competition from generics gets all of the profits on all of the unit sales:

103. When generic entry occurs, the brand manufacturer loses most of the unit sales; the generic manufacturers sell most of the units, but at drastically reduced prices; and competition delivers enormous savings to drug purchasers. Competition converts what formerly were excess profits into purchaser savings:

GENERIC COMPETITION DELIVERS SAVINGS TO PURCHASERS

104. To avoid this result, the brand manufacturer can pay the PBM to impair generic competition. The reduced competition keeps the brand manufacturer's profits high, and the manufacturer can use a portion of those extra profits to make the payment to the PBM. The brand manufacturer and the PBM win; purchasers lose:

PAYOFFS TO PBMS DIVIDE PURCHASER SAVINGS BETWEEN BRAND MANUFACTURERS AND PBMS



105. In order for this anticompetitive pact to work, the brand manufacturer needs a means by which to divide the extra profits with the PBM. The PBM will not help impair generic competition if it does not share in the ill-gotten gains. Kickbacks from the brand manufacturer are the way it divides the ill-gotten gains with the PBM.

106. As explained in detail below (see Sections VIII and IX), this case involves a cynical combination of these two generic-impairing tactics—a market switch enabled by kickbacks to the PBMs.

107. Biogen paid kickbacks—denominated as rebates and/or fees—to each of the Co-Conspirator PBMs. In exchange, the PBMs agreed not to favor lower cost generic Tecfidera over branded Tecfidera or Vumerity. Moreover, this had the intended effect of causing each of the PBMs to designate generic Tecfidera as a "specialty drug." That designation had devastating financial consequences for health plans and patients.

VII. BIOGEN'S DEVELOPMENT AND SALES OF TECFIDERA AND VUMERITY

A. Multiple Sclerosis Is a Chronic Disease for Nearly One Million Americans.

108. MS is a chronic autoimmune disease that affects the central nervous system. The disease is characterized by the immune system's attacking the protective sheath (myelin) that covers nerve fibers, leading to communication problems between the brain and the rest of the body. Almost one million people in the United States have been diagnosed with MS.

109. Although the symptoms and signs of MS can vary, the interruption of signals to the brain generally causes numbness, blindness, mood changes, memory problems, pain, fatigue, and/or paralysis. Other symptoms include lack of coordination, unsteady gait or inability to walk, prolonged double vision, blurry vision, vertigo, slurred speech, and cognitive problems.

110. MS most commonly presents in the relapsing remitting form. Patients will go through cycles of disease flair ups, experiencing symptoms that typically improve fully or partially over time. Remission of the disease tends to follow flair ups, but the length of remission varies.

111. The cost of living with MS is very high. Direct medical costs such as doctor's appointments and the cost of drugs are some of the biggest contributors to the high cost of living with MS. There is no cure for MS.

B. Biogen Made Billions Selling Tecfidera for More Than $90,000 Per Patient Per Year.

112. Biogen is a global biopharmaceutical company that manufactures, promotes, and distributes prescription drugs. On March 19, 2013, the U.S. Patent and Trademark office issued a patent for Tecfidera (dimethyl fumarate). In the same year, the FDA approved Tecfidera for the treatment of MS, and it quickly became one of Biogen's top-selling drugs. Biogen touted

Tecfidera's effectiveness in reducing MS relapses, delaying the progression of physical disability associated with MS, and slowing the development of MS-related brain lesions.

113. By 2015, Biogen's U.S. sales for Tecfidera were $2.9 billion, which was nearly half of Biogen's total U.S. product sales ($6.5 billion) for that year. Tecfidera's significant contribution to Biogen's U.S. sales continued throughout the rest of the decade:

Year	Tecfidera US Sales	Total Biogen US Product Sales
2016	$3.1 billion	$7.0 billion
2017	$3.2 billion	$7.0 billion
2018	$3.2 billion	$6.8 billion
2019	$3.3 billion	$6.7 billion

114. Biogen consistently raised Tecfidera's price to increase its total revenue and profits. For example, according to Biogen's 2016 Annual Report, "the increase in U.S. Tecfidera revenues was primarily due to price increases, partially offset by higher discounts and allowances and a decrease in unit sales volume of 1%." Biogen's Annual Reports likewise cited price increases as the reason for increased Tecfidera sales revenue from 2016 to 2017 and from 2018 to 2019.

115. Consequently, as of 2019 the average price of Tecfidera was $124.67 per pill (approximately $90,000 for an annual supply at two pills per day), up from an original 2013 price of about $71.87 per pill (approximately $52,500 for an annual supply at two pills per day)—a 73.5% increase. During that same period, the Consumer Price Index increased by only 9.7%.

116. Health plans allocated substantial financial resources to cover Tecfidera for their members. They assume the financial risk associated with providing healthcare benefits to their employees and members. Outrageously expensive drugs like Tecfidera (and, later, Vumerity)

place an enormous financial strain on these plans, including especially the plans sponsored by small-to-mid-sized employers and union health and welfare plans.

117. From 2013 until generic Tecfidera became available in 2020, branded Tecfidera was essentially a must-have for any formulary. It is a life-saving and life-altering drug, so PBMs had little choice but to include Tecfidera on their formularies. Excluding Tecfidera would have meant denying access to a primary therapy for MS patients.

118. All of that would change when generic Tecfidera became available.

VIII. BIOGEN'S PLAN TO DEFEAT GENERIC COMPETITION

A. Biogen Planned to Defeat Generic Competition with an "Evergreen" Strategy.

119. Beginning in 2017, Biogen found itself on the defensive as it confronted a series of challenges to its patent on Tecfidera. These patent challenges threatened Tecfidera's patent protections, which Biogen had relied on to secure its market exclusivity and significant revenue streams. Biogen knew that, if the patent challenges succeeded, early entry of generic competition would significantly reduce its profitability from this key product.

120. So Biogen developed a strategy to maintain the monopoly profits from its Tecfidera franchise even if its patent were invalidated. The plan was to "evergreen" the franchise by moving the Tecfidera prescriptions to a follow-on product before generic Tecfidera became available.

121. That follow-on product was Vumerity (diroximel fumarate). The development journey of Vumerity began with a U.S. patent application submitted in September 2013 by Alkermes plc, a Dublin-based pharmaceutical firm. This patent was issued on March 31, 2014 and expires on October 29, 2033.

122. Alkermes developed the formulation of diroximel fumarate in partnership with Biogen. Despite this early start in development, Biogen did not file a New Drug Application ("NDA") for diroximel fumarate until December 2018. The FDA granted approval for the drug in October 2019.

123. The way in which Biogen obtained FDA approval for Vumerity confirms that it is medically equivalent to Tecfidera. Biogen got FDA approval of Vumerity by using the studies that showed that *Tecfidera* was safe and effective. Biogen submitted studies showing that Vumerity is bioequivalent to Tecfidera.

124. Vumerity is diroximel fumarate, while Tecfidera is dimethyl fumarate. Although diroximel fumarate and dimethyl fumarate have different chemical structures and pharmacokinetic properties (how they are absorbed, distributed, and eliminated), the body rapidly converts both of them to the same active ingredient — monomethyl fumarate. It is that active ingredient that provides the drugs' therapeutic effects.

125. Similarly, the dosing regimens for the two medications share a common therapeutic strategy, which involves starting the patient on a lower dosage before escalating to a higher maintenance dose. A lower starting dosage allows the body to adjust to the new medication. Each Vumerity pill is 231mg. To start, the patient takes one pill (231mg) twice a day orally for 7 days. After 7 days, the patient increases the dosage to 2 pills (462mg) twice a day orally for maintenance. The Tecfidera starter pack includes pills that are 120mg each. To start, the patient takes one pill (120mg) twice a day orally for 7 days. After 7 days, the patient starts the maintenance dosage. This dosage contains pills that are 240mg each. And the patient takes one pill (240mg) twice a day orally for maintenance.

126. Biogen began selling Vumerity in 2019, marketing it on the asserted ground that it leads to fewer side effects—gastrointestinal problems—compared to Tecfidera. Medical professionals have met Biogen's marketing pitch with skepticism and outright denial.

127. An analysis of the clinical trial that serves as the basis for Biogen's claims suggests that the actual improvement in gastric intolerance with Vumerity is likely minimal, if it exists at all. Vumerity's purported average improvement was *one less day* of gastric upset. For MS patients who take these drugs over an extended time (as is typical) and for existing users of Tecfidera, there is no material difference.

128. Notably, the FDA-approved label for Vumerity does not include any claims of superiority of Vumerity over Tecfidera with respect to side effects or otherwise.

129. Instead, Vumerity is demonstrably *inferior* to Tecfidera. Switching from Tecfidera to Vumerity doubles the patient's pill burden—the number of pills the patient must take every day. And a patient's pill burden significantly affects the likelihood that she will adhere to the prescribed therapy. The fewer pills she must take, the more likely she is to adhere to the drug regimen, to avoid drug resistance, to have a better quality of life, and to have a better health outcome.

130. More than 25% of people with MS take five or more prescription medications. They often treat multiple symptoms with multiple medications which can lead to high medication or pill burden. Increasing the number of pills taken to treat the same symptoms does little to improve the treatment regimen for these patients. Failure to adhere to the therapy is associated with the development of drug resistance, toxicity, and lack of potency, among many other complications, including death.

131. Biogen's switching of the market from Tecfidera to Vumerity pushed patients in exactly the wrong direction in terms of pill burden, *doubling* the number of pills that patients are required to take. Vumerity was emphatically not a medical improvement over Tecfidera.

132. Biogen's own conduct confirms that conclusion. When it began selling Vumerity in October 2019, and continuing from that time to the present, Biogen sold Vumerity for *less than* Tecfidera. For example, in 2019 Biogen's list price for a day's supply of Tecfidera was $249, versus $228 for a day's supply of Vumerity. In 2021 the list prices were $258 for Tecfidera, versus $235 for Vumerity.

133. Biogen's promotional efforts in markets outside the United States further confirm that Vumerity is not a medical improvement over Tecfidera. In those non-U.S. markets, where Tecfidera still has patent protection, Biogen has continued to focus on promoting Tecfidera over Vumerity. In 2022, Biogen's Tecfidera sales outside the U.S. were more than $1 billion, 32 times higher than its Vumerity sales of just $32 million.

B. Biogen Planned, but Failed, to Switch the Market to Vumerity Before Generic Tecfidera Entered the Market.

134. As noted above (Section VI(a)), it was essential to Biogen's market-switch strategy that it move the prescription base from Tecfidera to Vumerity before generic Tecfidera became available.

1. Biogen Readied Vumerity If It Lost the Patent Litigation.

135. Biogen's patent protection was under attack on multiple fronts when Biogen filed for FDA approval of Vumerity in December 2018. Biogen sued several generic-drug manufacturers for patent infringement because they had filed ANDAs seeking FDA approval of their generic Tecfidera products. The generic manufacturers responded by alleging that Biogen's patent was invalid. If Biogen's patent had been upheld, it would not have expired until 2028.

136. One of the federal cases, between Biogen and Mylan Pharmaceuticals ("Mylan"), was pending in the Northern District of West Virginia. Biogen's other patent cases against generic manufacturers proceeded on a parallel track in the District of Delaware. Both cases were set for trial—one scheduled for December 2019 and the other for February 2020—when Biogen filed its NDA for Vumerity in December 2018.

137. In addition to the federal litigation, in February 2019, Mylan instituted an inter partes review ("IPR") challenge in the U.S. Patent and Trademark Office. Mylan's IPR proceeding also sought to invalidate the last remaining patent that protected Tecfidera, U.S. Patent No. 8,399, 514 (the "514 Patent").

138. Amid the uncertain climate of ongoing patent litigations for Tecfidera, Biogen told its investors that, if the Tecfidera patent was invalidated, it could switch the market to Vumerity. Biogen underscored this point, stating to investors that, "Importantly, ahead of the outcome of the IPR and District Court and the Litigations, we shall have the opportunity to launch VUMERITY, a novel oral fumarate disease-modifying treatment that has the potential to be another important choice for MS patients." Biogen explained that "[i]t is a priority that we appropriately maximize the potential of VUMERITY."

139. During that same investor call, an analyst asked, "Am I hearing it correct and also should we reasonably expect a meaningful switch ahead of IPR decision?" Biogen's CEO responded, "So from day one and this is the reason why we did the – we deployed capital and acquired this asset [the license from Alkermes] is that it was meaningful and strategically important for the company." He elaborated that "It would be premature to state on any clear tactical plan or strategy for launch. But while we speak, we are working thoroughly on that."

140. A month later, the CEO again told investors that "obviously, the patent situation will certainly have an entrance into the tactical plan of launching VUMERITY. But for that, we are working hard and time will tell, okay? The important situation, again, is that VUMERITY will be launched months or quarters before the court ruling on the [Tecfidera] IP."

141. Biogen later advised its investors that, "if we're unsuccessful with either the two district court cases, we've got VUMERITY as a product that we can kind of look at, is a fumarate strategy that we're looking at."

2. Biogen's Sole Motive Was to Impair Generic Tecfidera.

142. Biogen's sole motive in developing and marketing Vumerity was to use it in the evergreening strategy to defeat competition from generic Tecfidera. That exclusionary motive is confirmed by the fact that the strategy made economic sense for Biogen only because it had the effect of impairing generic competition. Biogen's decision to incur the extra costs (and suffer the revenue losses) associated with switching the market from Tecfidera to Vumerity was economically rational only because the switch had the exclusionary effect of impairing generic competition. But for the impact on generic competition, Biogen would not have invested the resources necessary to reformulate and cannibalize Tecfidera because doing so would have been a money-losing proposition.

143. Biogen knew when it was planning the switch that its combined sales of Tecfidera and Vumerity would be far less than its sales of Tecfidera before the switch. And as events played out, Biogen's forecast was correct.

144. Biogen incurred very substantial costs to garner these reduced sales. Biogen spent significant sums to develop Vumerity, obtain a patent that purportedly protected it, gain FDA approval, promote the product, and make royalty payments to Alkermes. Under the terms of their

operating agreement, FDA approval triggered a clause in which Biogen paid Alkermes $150 million for the worldwide commercial rights to Vumerity, along with 15% royalties on all sales.

145. If the switch did not have the effect of impairing generic competition, the switch would have been a money-losing proposition for Biogen. The conduct made economic sense for Biogen solely because it did have the effect of impairing generic competition. Biogen's investments in reformulating and cannibalizing the sales of Tecfidera were not investments in improving products and helping patients; they were investments in impairing competition.

3. Biogen Botched the Timing of the Market Switch.

146. Biogen knew that if it switched the prescription base to Vumerity before generic Tecfidera entered the market, doctors would not later switch them back to generic Tecfidera. Patients stay on a particular MS medication for long periods of time. Those patients like to stay on a drug once they find one that works. They do not want to risk unnecessary symptoms or complications by switching drugs.

147. Consequently, Biogen knew that if it switched the market before generic Tecfidera was available, the generics would make very few sales because, by that time, Biogen would have all but eliminated the Tecfidera prescription base. Biogen would have deprived the generics of their only cost-efficient means of competing for sales.

148. The trouble for Biogen started with the outbreak of the COVID-19 pandemic in March 2020. Biogen's market-switch strategy relied on in-person sales pitches to the prescribing doctors. Given the minimal-to-non-existent clinical differences between Tecfidera and Vumerity, Biogen needed to rely on personal contacts with the doctors to convince them to switch.

149. Those in-person contacts became very difficult once COVID-19 hit. Biogen later reported to its investors that "it's important to note that the MS market in the US has been

significantly impacted by lower new patient starts and switches due to COVID-19, as well as reduced engagement with physicians, which have both impacted the launch of VUMERITY."

150. Another problem arose when Biogen was unable to settle the patent lawsuits with the generic manufacturers. In July 2019, Biogen told its investors that "there was a lot of interest" in settling the patent litigations. Biogen anticipated that it could settle the patent litigations with agreements by the generic manufacturers to delay entering the market until years later. Biogen would use that delay to switch the market from Tecfidera to Vumerity.

151. Biogen's confidence that it could get delay through settlements was misplaced. It was unable to reach settlements with Mylan and other generic manufacturers before those cases went to trial. The bench trial in the Delaware case went forward in December 2019, and the bench trial in the West Virginia case proceeded in February 2020.

152. On June 18, 2020, the U.S. District Court for the Northern District of West Virginia found that Biogen's '514 patent was invalid. The District Court in Delaware reached the same conclusion on September 16, 2020.

153. After the first decision, in July 2020, Biogen advised investors that "[g]oing forward, our strategic focus is now on VUMERITY, and we are increasing our resource allocation to maximize this next-generation fumarate." The CEO emphasized that "now the entire focus is pivoting on VUMERITY…." Biogen was making "a significantly enhanced focus of the organization on one brand, VUMERITY."

154. Biogen's Executive VP & Chief Medical Officer had told investors in 2019 that "physicians that I talked to would not want to switch somebody who's done well who's stabilized [after] the initial phases of taking TECFIDERA and are doing well in terms of

tolerability." But Biogen abruptly changed its position once competition from generic Tecfidera was imminent.

155. Biogen started using its army of sales force detailers to cannibalize the Tecfidera prescriptions, i.e., to aggressively switch them to Vumerity. Among many other marketing tactics, Biogen implemented "incentive schemes" for its salesforce, conditioning top pay to converting as many Tecfidera prescriptions as possible to Vumerity.

156. Beginning in late 2020, patient attempts to visit the Tecfidera webpage were automatically intercepted by a different webpage informing them of another option – Vumerity. From that page, patients could either choose to visit the Vumerity webpage or continue to the Tecfidera site.

157. Even after losing both of the patent cases in the district courts, Biogen thought it still had time to switch the market to Vumerity before the entry of generic Tecfidera. When the brand drug has sales of the magnitude that Tecfidera achieved—more than $3 billion annually—generic manufacturers will sometimes wait to enter the market despite a win in the district court. They wait until their trial-court victory is affirmed on appeal. If they enter the market and the patent victory is later overturned on appeal, they are liable to the brand manufacturer for patent

infringement. On a drug like Tecfidera, the patent-infringement damages can be very substantial, and generic manufacturers are not always willing to take that kind of risk.

158. Accordingly, Biogen told its investors in July 2020—after Biogen's first loss to a generic manufacturer at trial—that Biogen "assumed no generic entry for Tecfidera" in 2020. But Biogen's planning was wrong again. Its patent was so weak that the generic manufacturers did not wait for an appellate decision before entering the market.

159. On August 17, 2020, the FDA approved Mylan's ANDA for dimethyl fumarate. Mylan announced the launch of its generic Tecfidera capsules on August 19, 2020. Several additional generic competitors entered the market over the ensuing months.

160. Biogen's plan to switch the market to Vumerity before the generics entered the market was in shambles.

IX. BIOGEN PAID THE PBMS TO IMPAIR COMPETITION FROM GENERIC TECFIDERA.

161. Biogen's poor timing on the market switch prevented it from substantially impairing generic competition acting on its own. To achieve that anticompetitive goal, it had to enlist other industry participants—the PBMs.

162. Biogen had planned to impair generic competition by switching the market from Tecfidera to Vumerity before generic Tecfidera became available for sale. But COVID-19 made the switch more difficult, and generic Tecfidera became available much sooner than Biogen anticipated. So Biogen turned to a different plan. Even though generic Tecfidera was *available for sale*, Biogen paid the PBMs to ensure that it was *not in fact dispensed to patients*. Biogen used this period of impaired generic competition to switch as many prescriptions as possible from Tecfidera to Vumerity.

163. With the impending entry of generic Tecfidera, the PBMs finally had the opportunity to generate huge savings for the health plans and the insureds. The generics usually take 90% of the brand sales within 10 months of generic entry. And the generics sell at massive discounts off the brand price.

164. Instead, Biogen enlisted the PBMs in an anticompetitive scheme to thwart that robust competition. In July 2020 Biogen's CEO admitted that

> since the focus now is on VUMERITY not on the fumarate, I can tell you that all levels [at Biogen] are aligned, at the payer level, at the patient services level, at the salesforce level - including incentive schemes -- to shape their behavior, at the medical affairs level. So, the organization is absolutely aligned and focused on all of those levers.

As described below, Biogen pulled the "levers" by paying off the PBMs to help impede the generic competition that it was the PBMs' job to promote.

A. Biogen Paid Increased Rebates and Fees to PBMs for Impairing Generic Tecfidera.

165. Biogen conditioned the PBMs' receipt of additional rebates and fees on the PBMs' refusing to promote generic Tecfidera on their formularies.

166. When generics became available, the PBMs had the unquestioned ability to drive the uptake of generic Tecfidera—or to impair and delay that uptake. Absent some anticompetitive purpose, PBMs almost always heavily promote the low-price generic substitute. For example, CVS Health's Form 10-K for 2023 states that the company "helps its PBM clients control costs by recommending plan designs that encourage the use of generic equivalents of brand name drugs when such equivalents are available."

167. As noted above, the PBMs' principal way to promote generics is to place them on the lowest (the best) tier on the formulary—Tier 1. Correspondingly, the PBMs place the counterpart brand drug on the highest (the worst) tier—Tier 5.

168. **Of course** a PBM that has not been paid off will promote the generic. Generics sell at a small fraction of the brand's price. Here, within seven months of entering the market the generics were selling for $17 per pill while brand Tecfidera was $132 per pill.

169. Biogen paid each of the three PBMs (and others) to not promote or advantage generic Tecfidera over brand Tecfidera or Vumerity. It paid increased rebates and fees to PBMs if they agreed not to place the generics on a better tier than branded Tecfidera and Vumerity.

170. The PBMs passed *some* of the *rebates* on to *some* of their customers. They did not pass on any of the relevant unearned *fees*, which account for a substantial portion of the total kickbacks.

171. The PBMs are not buyers of Tecfidera, Vumerity or of the competing generic products. The PBMs are agents that negotiate formulary placement and prices on behalf of the health plans and the insureds. In paying the rebates and fees to the PBMs, Biogen was not competing with generic Tecfidera on price. It was paying agents—the PBMs—to impair that competition and thereby give Biogen time to conduct the market switch.

172. This is confirmed empirically by the basic economics. In 2022 the average acquisition cost for generic Tecfidera was just $10 per pill—more than 93% off the list price of branded Tecfidera. In contrast, Biogen's average rebates and fees (combined) on branded Tecfidera—even if they had been fully passed on by the PBMs to their health-plan clients—would have resulted in a net price just 28% off the list price. Biogen was not competing on price to win the health plans' business. It was paying the health plans' agents to undermine the generic competition that it was their job to promote.

173. The conclusion is no different when examining retail prices rather than acquisition cost. For example, in 2022 the typical retail price for generic Tecfidera was about

$25 per pill, versus an average net price—even if all rebates and fees had been passed on to the health plans—of $100 per pill for brand Tecfidera. Notably, the average retail prices for generic Tecfidera were artificially increased by Biogen's manipulation of the formularies. Pharmacies that sold generic Tecfidera outside the PBM ecosystem—pharmacies like Mark Cuban's Cost Plus Drug Company—charged a retail price of only $1 per pill.

174. Biogen's rebates and fees were payments *to the PBMs* in exchange for impairing the generics, not price reductions to the health plans that, even if fully passed on to them, would have produced savings anywhere near what the generics offered. The rebates and fees were not competitive price reductions to health plans; they were kickbacks to those plans' faithless agents in exchange for their help in impairing competition.

175. That conclusion is further reinforced by the change in the amount of rebates/fees that Biogen paid based on the *timing* of its market switch. Biogen paid the highest rebates/fees on Tecfidera in the key year 2021 as it worked feverishly to switch the market from Tecfidera to Vumerity. The average rebates/fees rose from 12% of the list price in 2019, to 19% in 2020 (the generics did not enter until Fall 2020), to the *high point of 45% in 2021*, and then declined to 28% in 2022, and 27% in 2023. Biogen was paying the PBMs for their help in making the market switch; it paid the highest rebates/fees in the year that it most needed their help to impair generic competition and make the switch.

176. Biogen was not paying these rebates/fees to win the health plans' business by competing with generic Tecfidera on price. If Biogen had been doing that, the list price of Tecfidera minus all rebates/fees would have been close to the price of generic Tecfidera and would have declined as the price of generic Tecfidera declined. That is not at all what happened.

177. Instead, the list price of Tecfidera minus all rebates/fees fell from $115 per pill in 2019, to $112 in 2020 (the generics did not enter until Fall 2020), to the *low point of $75 in 2021*, and then *rose* substantially to $100 in 2022, and $110 in 2023. In contrast, the retail prices of generic Tecfidera were dramatically lower, and they substantially *and steadily* decreased over time. They did not, as Biogen's net prices did, increase after the critical year 2021. They continued to substantially decline.

178. If Biogen were competing on price for the health plans' business, it could have simply offered them a low net price. Biogen and the PBMs decided to use "rebates" and fees rather than low net prices to the health plans and insureds. And even if Biogen had some unknown but legitimate reason to use rebates and fees rather than a low net price, it made the choice to pay the rebates and fees to the PBMs rather than to the health plans. Biogen paid rebates and fees to the PBMs because it was paying them off to help impair the generic competition that it was their proper role to promote.

179. And the PBMs knew that Biogen was using the competition-impaired time that it bought from them to switch the market from Tecfidera to Vumerity. The PBMs did not initially favor Vumerity over Tecfidera on their formularies. If Vumerity had medically significant advantages over Tecfidera, in terms of clinical effectiveness or patient tolerability, the PBMs would have placed Vumerity in a superior position on their formularies as soon as Vumerity was available. They did not.

180. The PBMs participated in the anticompetitive scheme and actively facilitated it because Biogen handsomely paid them to do so.

B. Biogen's Scheme Caused PBMs to Designate Generic Tecfidera a Specialty Drug.

181. Biogen's requirement that the PBMs not disadvantage Tecfidera or Vumerity compared to generic Tecfidera resulted in many of their formularies designating generic Tecfidera as a specialty drug.

182. Nothing about generic Tecfidera required special handling—it is a shelf-stable pharmaceutical dispensed in pill format. Nor did it carry a high price which sometimes results in PBMs designating a product a "specialty drug." This was not a legitimate designation for generic Tecfidera.

183. Instead, the purpose and effect of Biogen's causing that designation was to make patients incur a very high copayment or coinsurance for generic Tecfidera, significantly reducing their incentive to accept the generic. Another purpose and effect was to require that the falsely designated product be dispensed only through a small number of specialty pharmacies, shielding those pharmacies—owned by the PBMs—from price competition from all other pharmacies. Biogen knew and intended that this would substantially depress the sales of generic Tecfidera by keeping its price to health plans and other purchasers astronomically high.

184. The concentration and vertical integration in the PBM industry ensured that competition among the PBMs would not dissuade any one of them from designating generic Tecfidera as a specialty drug. All three are affiliated with a specialty pharmacy; all three shared a desire—absent effective competition among them—that its specialty pharmacy make these outlandish profits on the sale of generic Tecfidera; and each of the three knew that Biogen was offering the same kickbacks to the other two.

185. Indeed, the PBM-affiliated specialty pharmacies bought generic Tecfidera from the manufacturers for as little as $180 for a 30-day supply; they sold it to the health plans and their insureds for as much as $3,857.

186. The artificially high price that the PBM-affiliated specialty pharmacies charged to health plans for generic Tecfidera also had the intended effect of making the prices of branded Tecfidera and Vumerity appear to be more reasonable than they were. The artificially high price of the generic made the price of branded Tecfidera and Vumerity—plus some share of rebates—seem like a better deal than it really was for health plans and insureds.

187. If generic Tecfidera had been available to the health plans *at a competitive price*—for, say, $3 per pill rather than the artificial $64 per pill through the specialty pharmacy—health plans would have seen the prices of branded Tecfidera and Vumerity (even with some share of the rebates) as the rip-off that they were.

188. The artificially high price of generic Tecfidera through the specialty pharmacies had the effect that Biogen intended. It resulted in continued sales of branded Tecfidera and Vumerity at supracompetitive prices. The PBMs went along with the anticompetitive scheme because Biogen paid them to.

X. BIOGEN'S CORRUPT AGREEMENTS WITH THE PBMS SUPPRESSED GENERIC COMPETITION.

189. Biogen's conduct had its intended effect of significantly impairing competition from generic Tecfidera.

A. OptumRx's Formularies

190. OptumRx serves as the PBM for UnitedHealth Group, Inc. ("UHG"), and it has been identified as one of UHG's "four reportable segments" (along with UnitedHealthcare,

Optum Health, and Optum Insight). OptumRx's revenue contributes more than one third of UHG's overall revenues, which exceeded $371 billion in 2023.

191. OptumRx manages approximately 22% of pharmacy benefit services in the U.S. and provides those services for over 66 million covered lives. It also operates a network of more than 67,000 pharmacies.

192. In 2023, OptumRx managed pharmaceutical spending of $159 billion, which included $63 billion in specialty pharmaceutical spending. OptumRx's revenue in 2023 exceeded $116 billion.

193. In 2023 Optum Specialty Pharmacy earned $32.3 billion in revenues from specialty pharmacy drugs. This represented 13% of prescription revenues from specialty pharmacy drugs in the U.S.

194. UHG offers a spectrum of products and services including health insurance plans through its wholly owned subsidiaries. UHG reported that it received from drug manufacturers rebates of $8.2 billion in 2022, and $11 billion in 2023. It did not report the additional "fees" that it received, including those received by its offshore rebate aggregator, Emisar.

195. In exchange for the kickbacks from Biogen, OptumRx agreed not to advantage or promote generic Tecfidera on many of its formularies relative to Tecfidera or Vumerity. And this also caused OptumRx to designate generic Tecfidera as a specialty drug on many formularies.

196. As a consequence, in 2020 formularies governing more than 34% of OptumRx's covered lives did not give generic Tecfidera any better treatment than Tecfidera or Vumerity on

the formulary.[1] *In the key year of 2021 the number jumped to 49%.* Then it declined to "only" 37% in 2022 and 36% in 2023.

197. The kickbacks also caused very substantial numbers of health plans and insureds to pay "specialty drug" prices—as much as $3,857 or more for a 30-day supply—for *generic* Tecfidera. For each year from 2020 through 2023, formularies governing at least 20% of OptumRx's covered lives designated generic Tecfidera as a specialty drug.

198. Absent Biogen's kickbacks, generic Tecfidera would have been treated like essentially all generic drugs that are not subject to anticompetitive pacts—it would have been placed on Tier 1 on all of OptumRx's formularies. Instead, in 2020 formularies governing more than 41% of OptumRx's covered lives did not have generic Tecfidera on Tier 1. *In the key year of 2021 that number jumped to 73%.* Then it declined to "only" 54% in 2022 and 57% in 2023.

199. Just like the data regarding rebates/fees, not only the magnitude of these percentages, but their pattern, confirm Biogen's scheme to pay off the PBMs to enable the market switch from Tecfidera to Vumerity. Biogen succeeded in coopting OptumRx to enable the market switch in the key year 2021.

B. CVS Caremark's Formularies

200. CVS Caremark manages approximately 34% of pharmacy benefit services in the U.S. and provides those services for approximately 108 million covered lives. CVS Caremark operates the largest chain of retail pharmacies in the country, with more than 9,000 locations.

201. In 2023 CVS Specialty's revenues were $73.3 billion from sales of specialty drugs. This represented 30% of prescription revenues from all specialty drugs nationwide.

[1] Managed Markets Insight & Technology, LLC, is the source for many of the formulary data summaries alleged herein.

202. In 2018, CVS Health Corp., acquired Aetna for $69 billion and became the first combination of a major health insurer, PBM, and mail-order and retail pharmacy chain. As a result, CVS Health Corp. controls the health plan/insurer and PBM services provided to Aetna, the third largest health insurer in the U.S. In 2023, Aetna reported revenue of approximately $105.6 billion. It offers medical, pharmacy, and other insurance plans in the commercial, Medicare Advantage, and Managed Medicaid markets.

203. In exchange for the kickbacks from Biogen, CVS Caremark agreed not to advantage generic Tecfidera on many of its formularies relative to Tecfidera or Vumerity. And this also caused CVS Caremark to designate generic Tecfidera as a specialty drug on many formularies.

204. As a consequence, in 2020 formularies governing more than 21% of CVS Caremark's covered lives did not give generic Tecfidera any better treatment than Tecfidera or Vumerity on the formulary. In the key year of 2021 the number nearly doubled, to 38%. The number was 36% in 2022 and 39% in 2023.

205. The kickbacks also caused very substantial numbers of health plans and insureds to pay "specialty drug" prices—as much as $3,857 or more—for *generic* Tecfidera. In 2020 formularies governing 11% of CVS Caremark's covered lives designated generic Tecfidera as a specialty drug. In the key year 2021 that number almost doubled, to 20%. It was 18% in 2022, and 19% in 2023.

206. Absent Biogen's kickbacks, generic Tecfidera would have been treated like essentially all generic drugs that are not subject to anticompetitive pacts—it would have been placed on Tier 1 on all of CVS Caremark's formularies. Instead, in 2020 formularies governing

more than 41% of CVS Caremark's covered lives did not have generic Tecfidera on Tier 1. In the key year of 2021 that number jumped to 49%. It was 47% in 2022 and in 2023.

C. Express Scripts' Formularies

207. Express Scripts manages approximately 23% of pharmacy benefit services in the U.S. and provides those services for more than 100 million covered lives.

208. Cigna, which merged with Evernorth in 2018, is the fourth largest health insurer in the U.S. It offers commercial and Medicare Advantage medical, pharmacy and other insurance plans. As a result, the Evernorth corporate family controls the health plan/insurer, the PBM, and the mail order pharmacies used by approximately 15 million Cigna members in the U.S.

209. Evernorth reported to its shareholders that it "operates various group purchasing organizations that negotiate pricing for the purchase of pharmaceuticals and formulary rebates with pharmaceutical manufacturers on behalf of their participants" and operates the company's Pharmacy Rebate Program while its subsidiary Express Scripts provides formulary management services. In 2021, Evernorth reported adjusted revenues of $131.9 billion (representing 75.8% of the Cigna's revenues), which was up from $116.1 billion in 2020. In 2023 Evernorth reported its adjusted revenues as exceeding $153 billion.

210. Express Scripts' specialty pharmacy, Accredo, earned $59.5 billion in revenues in 2023. This was a 24% share of prescription revenues from all specialty pharmacy drugs nationwide.

211. In exchange for the kickbacks from Biogen, Express Scripts agreed not to advantage generic Tecfidera on many of its formularies relative to Tecfidera or Vumerity. And this also caused Express Scripts to designate generic Tecfidera as a specialty drug on many formularies.

212. As a consequence, in 2020 formularies governing more than 24% of Express Scripts' covered lives did not give generic Tecfidera any better treatment than Tecfidera or Vumerity on the formulary. In the key year of 2021 the number rose to 34%. The number then declined to 14% in 2022 and in 2023.

213. The kickbacks also caused very substantial numbers of health plans and insureds to pay "specialty drug" prices—as much as $3,857 or more—for *generic* Tecfidera. In 2020 formularies governing 5% of Express Scripts' covered lives designated generic Tecfidera as a specialty drug. In the key year 2021 that number tripled, to 15%. It was 12% in 2022 and in 2023.

214. Absent Biogen's kickbacks, generic Tecfidera would have been treated like essentially all generic drugs that are not subject to anticompetitive pacts—it would have been placed on Tier 1 on all of Express Scripts' formularies. Instead, in 2020 formularies governing more than 29% of Express Scripts' covered lives did not have generic Tecfidera on Tier 1. In the key year of 2021 that number jumped to 36%. It then declined to 19% in 2022 and in 2023.

D. The Cumulative Numbers

215. The three PBMs manage the pharmacy benefits for approximately 80% of all patients in the U.S. But Biogen made the same corrupt bargain with other major PBMs too.

216. All told, in the key year 2021 more than 45% of the 300 million Americans with pharmacy benefit coverage were covered by formularies that did not give generic Tecfidera any better tier placement than Tecfidera or Vumerity. In that year, 17%—52 million people—were subjected to formularies that designated generic Tecfidera as a "specialty" drug. And 54%—164 million Americans—were governed by formularies that did not place generic Tecfidera on Tier 1.

217. The reality was (and is) even worse than these numbers imply. In PBMs to impair generic competition, Biogen achieved an anticompetitive effect beyond the significant harm implied by simply adding the individual numbers.

218. When formularies that govern a significant portion of prescriptions restrict access to a less expensive generic like dimethyl fumarate, that limited access has a negative *spillover effect* at the prescriber level.

219. A doctor who repeatedly encounters difficulty prescribing a certain medication (because it is not preferred by a PBM) is less likely to prescribe that product, including for patients who are not members of that health plan. A doctor's patients are covered by many different health plans, and each health plan covers different products. Instead of researching each patient's coverage before prescribing a product, doctors tend to default to the product they know is preferred on most formularies. The aggregate effect is that if a given product is not preferred on a substantial number of formularies, doctors will tend to prescribe a product that is preferred.

220. Accordingly, the intended effect of Biogen's impairing generic Tecfidera on many formularies was that doctors were much more likely to prescribe Vumerity. They did so even for patients whose health plans did not disadvantage the generics. And the formularies that did prefer generic Tecfidera were less able to drive sales toward the generics.

221. This spillover effect from Biogen's unlawful payments made their anticompetitive conduct even worse than it appears when measured only by covered lives under the formularies as to which Biogen paid the kickbacks.

E. The Resulting Massive Increases in Biogen's Branded Sales.

222. Biogen's payoffs to the PBMs worked. In June 2020, before the courts invalidated Biogen's patent and it started switching the market in earnest, Vumerity had monthly unit sales of just 50,000. With the PBMs' substantial help in impairing generic competition, by June 2021

Vumerity's monthly unit sales had rocketed to more than 423,000. Almost all of those sales came from prescriptions that would have been for Tecfidera and substituted with the generic.

223. Had Biogen not paid the PBMs to enable the market switch from Tecfidera to Vumerity, by June 2021 90% or more of the relevant prescriptions would have been filled with generic Tecfidera. That is the typical sales-erosion rate for branded prescription-drug pills. The significant erosion of sales of branded Tecfidera would have, in turn, dramatically limited the Tecfidera prescription base available for Biogen's sales force to switch to Vumerity.

224. Instead, Biogen's payoffs to the PBMs prevented generic Tecfidera from taking the typical 90% of sales. Due to Biogen's unlawful conduct, in that timeframe generic Tecfidera was able to take *less than a third* of the sales.

225. Thus, just as Biogen intended, its unlawful conduct significantly: (a) slowed the erosion of Tecfidera sales; and (b) artificially inflated the number of prescriptions for Vumerity. Those sales of branded Tecfidera and Vumerity came at the expense of the dramatically less expensive generic Tecfidera.

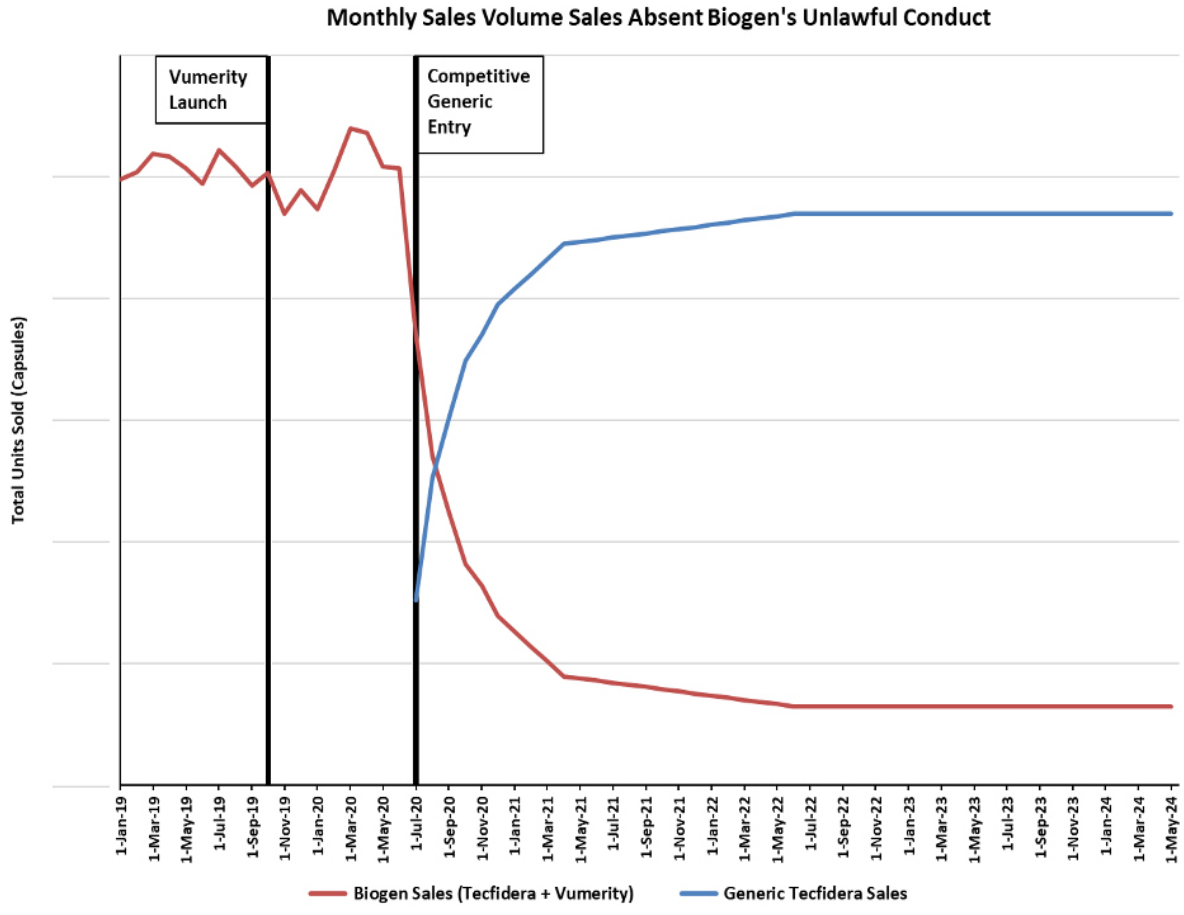
226. That conclusion is confirmed by focusing on the timeline for sales of Vumerity. Based on Vumerity's medical merit—its *lack* of substantial improvement over Tecfidera—without Biogen's payoffs Vumerity would have achieved unit sales of less than 5% of the monthly unit sales that branded Tecfidera had in July 2020.

227. That very modest sales figure for Vumerity is readily confirmed. First, Biogen's own clinical studies show that, at most, only about 4% of patients benefit from taking Vumerity rather than Tecfidera over a five-week period. And, as noted above, medical professionals have doubted even that purported small benefit.

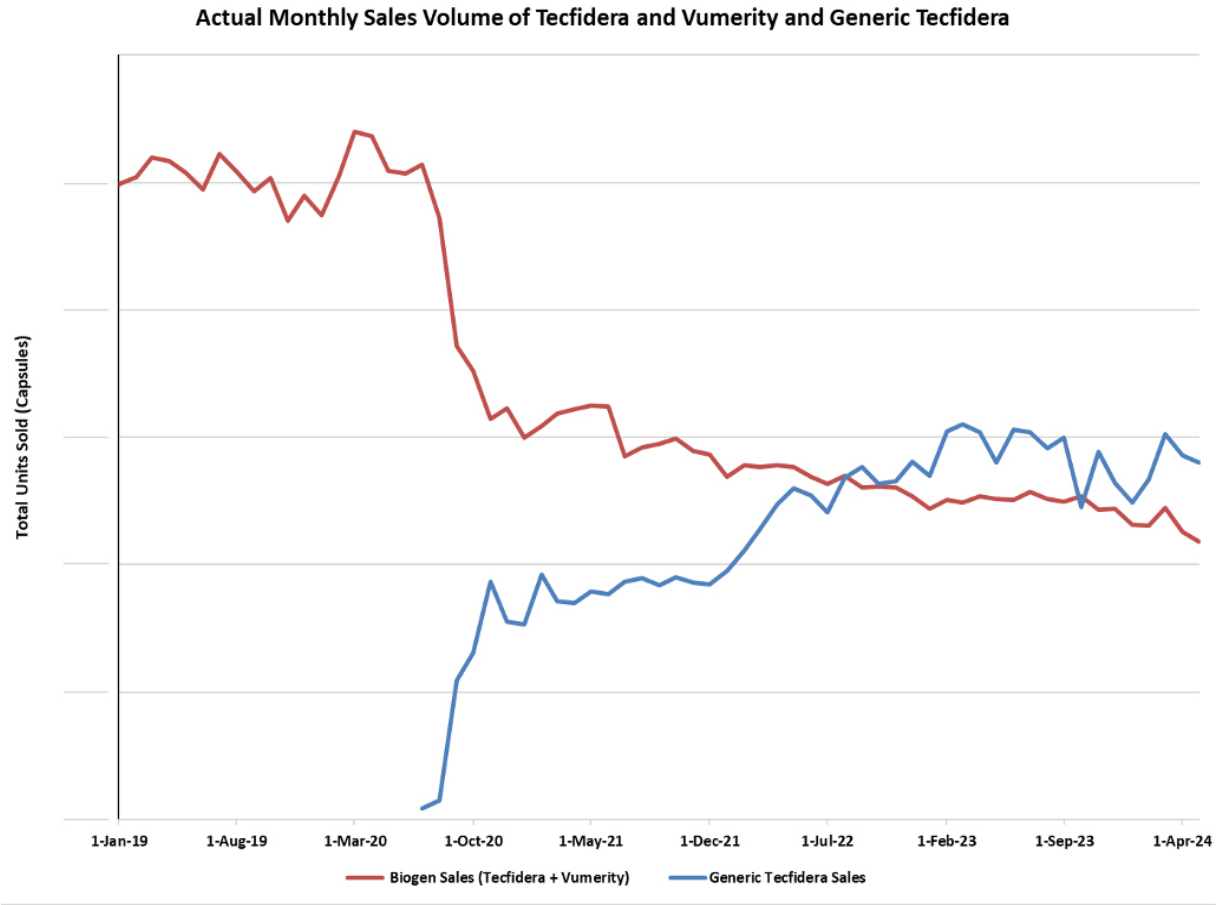
228. Second, before Biogen began paying the PBMs, Vumerity had been on the market for more than eight months but had achieved monthly unit sales of only 50,225 capsules (equal to only 419 thirty-day supplies at four capsules per day). That was just 2% compared to Tecfidera's sales of 2,495,616 capsules (equal to 41,594 thirty-day supplies at two capsules per day), and only 1.0% when measured in standardized 30-day supplies.

229. Just as Biogen intended, its unlawful conduct significantly and artificially inflated the sales of both Tecfidera and Vumerity. Those sales came at the expense of the dramatically less expensive generic Tecfidera.

230. Absent Biogen's unlawful conduct, its combined unit sales of branded Tecfidera and Vumerity, compared to sales of generic Tecfidera, would have looked approximately like this:



231. As a result of Biogen's payoffs to the PBMs, its actual combined unit sales of branded Tecfidera and Vumerity during that same timeframe, compared to sales of generic Tecfidera, looked approximately like this:



232. To overcome the price disconnect in pharmaceutical markets, Congress and every State promote the distribution of generic drugs through automatic substitution at the pharmacy counter. That automatic substitution is generic manufacturers' cost-efficient means of competing. Biogen's payoff-enabled market switch substantially impaired generic manufacturers' cost-efficient means of competing, and deprived health plans and insureds of the benefits of that competition.

233. Biogen's market switch substantially foreclosed generic competition by denying generic manufacturers a fair opportunity to compete using state generic-substitution laws. Biogen's kickback-enabled campaign to switch patients to Vumerity effectively coerced patients and Class members to purchase brand Tecfidera and Vumerity despite the availability of more affordable generic Tecfidera.

234. Only brand manufacturers—not generic manufacturers—pay rebates and fees to PBMs. So the PBMs shared Biogen's goal of seeing as many prescriptions as possible switched from Tecfidera to Vumerity, not to the generic. The PBMs will go on collecting rebates on Vumerity into the future—the patents on Vumerity do not expire until 2033.

235. Manufacturers do not pay any rebates or fees to PBMs on generic Tecfidera. The economic benefits of generic Tecfidera flow to actual drug purchasers, not to their faithless agents, the PBMs.

236. Biogen's impairment of competition from generic Tecfidera during the period August 2020 to April 2024 cost purchasers more than $3 billion in lost savings. Biogen's anticompetitive conduct prevented purchasers from substituting generic Tecfidera for branded Tecfidera, and permitted Biogen to switch a substantial portion of the market from Tecfidera to Vumerity, for which generic Tecfidera is not substitutable.

237. Those losses continue to pile up, and will go on piling up absent effective injunctive relief from this Court. As of May 2024, Vumerity has a sales base of more than a million units per month. No generic is available for that product. Absent Biogen's unlawful conduct, Vumerity would have a prescription base of less than 200,000 units per month.

238. Bottom line: health plans and insureds are paying for the difference. They are paying for more than 800,000 units per month for branded Vumerity that, absent Biogen's

unlawful conduct, would have been filled with generic Tecfidera. The difference in cost for the brand Vumerity versus generic Tecifidera for those prescriptions is a staggering $655 million per year. Absent effective injunctive relief, those overcharges could continue until 2033.

239. Those two elements of loss—the initial overcharges of more than $3 billion for the period August 2020 to April 2024, and the ongoing overcharges of $655 million per year—do not exhaust the losses. The economic losses from designating generic Tecfidera as a specialty drug are not included in those amounts. The specialty drug part of the scam has already cost health plans an estimated additional $500 million. Those losses, too, are continuing.

XI. THE SCHEME'S ANTICOMPETITIVE EFFECTS

240. Biogen's scheme and payments to suppress generic competition to Tecfidera have delayed and substantially diminished the sale of generic Tecfidera. By delaying the onset of full generic competition and decimating the prescription base, Biogen deprived would-be generic manufacturers of the most efficient means of distribution under the governing statutes and regulations.

241. Biogen's anticompetitive conduct, and the PBMs' participation in it, delayed and substantially diminished the sale of generic Tecfidera in the United States, and unlawfully enabled Biogen to sell Tecfidera and Vumerity at artificially inflated units and prices. But for Biogen's illegal conduct, generic manufacturers would have been able to enter the market unimpeded and compete on the merits against Tecfidera and Vumerity. Biogen's conduct unlawfully prevented purchasers of Tecfidera and Vumerity from obtaining the benefits of unimpaired generic competition.

242. Biogen's scheme and unlawful payments harmed Plaintiff and the Class by depriving them of a market in which: (1) the prescription base available for automatic generic

substitution is determined by unrestrained competition; (2) they receive the honest services of PBMs, untainted by kickbacks for promoting higher-priced branded drugs rather than generics; (3) generic drug manufacturers have unimpaired access to the most cost efficient means of distribution; and (4) follow-on branded products must compete on the merits, unaided by kickbacks that enable and facilitate a market switch designed to impair generic competition.

243. But for Biogen's unlawful conduct: (1) by June 2021 about 90% of prescriptions for Tecfidera would have been filled with the much less expensive generic Tecfidera; and (2) Biogen would have been able to switch few Tecfidera prescriptions to Vumerity.

244. Biogen's unlawful conduct has delayed and diminished the sale of generic Tecfidera in the United States, and unlawfully enabled Biogen to sell Tecfidera and Vumerity at artificially inflated, supracompetitive prices. As a consequence, Plaintiff and other Class members have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

XII. CLASS ACTION ALLEGATIONS

245. Plaintiff brings this action on behalf of itself and, under Fed. R. Civ. P. 23(a), 23(b)(2), and (b)(3), as representative of a Class defined as follows:

> All persons or entities in the United States and its territories, not including natural persons, who purchased, paid and/or provided reimbursement for some or all of the purchase price for Vumerity, Tecfidera, and/or its AB-rated generic equivalents in any form, for consumption by their members, employees, insureds, participants, or beneficiaries (the "Class"), other than for resale, during the period August 19, 2020 through and until the anticompetitive effects of Biogen's unlawful conduct cease (the "Class Period").

246. The following persons or entities are excluded from the proposed Class:

a. Biogen and its officers, directors, management, employees, subsidiaries, or affiliates;

b. Pharmacy benefit managers;

c. Health plans in the same corporate family as a pharmacy benefit manager;

d. All federal or state governmental entities, excluding cities, towns or municipalities with self-funded prescription drug plans;

e. All persons or entities who purchased Vumerity, Tecfidera, or its AB-rated generic equivalent, for purposes of resale or directly from Biogen or its affiliates;

f. Fully insured health plans (i.e., Plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members); and

g. Any third-party payors that purchased Tecfidera but did not pay and/or provide reimbursement for any AB-rated generic equivalent after such generics became available.

247. Class members are so numerous that joinder is impracticable. Plaintiff believes that the Class includes thousands of third-party payors.

248. Plaintiff's claims are typical of those of the Class members. Plaintiff and all Class members were damaged by the same wrongful conduct of Biogen, i.e., they paid artificially inflated prices for Tecfidera and Vumerity and were deprived of the benefits of more robust competition from cheaper generic versions of Tecfidera as a result of Biogen's wrongful conduct.

249. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

250. Plaintiff is represented by counsel with experience in the prosecuting class action antitrust litigation, and with particular experience in class action antitrust litigation involving pharmaceutical products.

251. Questions of law and fact common to the Class members predominate over questions that may affect only individual Class members because Biogen has acted on grounds generally applicable to the entire Class, thereby making overcharge damages with respect to the

Class as a whole appropriate. Such generally applicable conduct is inherent in Biogen's wrongful conduct.

252. Questions of law and fact common to the Class include, but are not limited to:

a. whether Biogen conspired to suppress generic competition to Tecfidera;

b. whether Biogen and one or more of the three PBMs entered into an unlawful agreement in restraint of trade;

c. whether, pursuant to the agreement, one or more of the PBMs agreed to disfavor generic Tecfidera on its formularies;

d. whether, pursuant to the agreement, Biogen compensated the PBM;

e. whether Biogen's compensation to the PBM was necessary to yield some procompetitive benefit that is cognizable and non-pretextual;

f. whether the agreement is illegal under the rule of reason;

g. whether Biogen switched the market from Tecfidera to Vumerity in order to impair competition from generic Tecfidera;

h. whether the law requires definition of a relevant market when direct proof of market power is available and, if so, the definition of the relevant market;

i. whether Biogen's conduct as alleged herein has substantially affected interstate commerce;

j. whether, and to what extent, Biogen's conduct caused antitrust injury (i.e., overcharges) to Plaintiff and the Class members; and

k. the quantum of aggregate overcharge damages to the Class.

253. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured

persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweigh potential difficulties in management of this class action.

254. Biogen's anticompetitive conduct has imposed and will continue to impose (unless the Court grants effective equitable relief) a common antitrust injury on Plaintiff and all Class members. Biogen's anticompetitive conduct and its relationships with the Class members have been substantially uniform. Biogen has acted and refused to act on grounds that apply to the class generally, and injunctive and other equitable relief is appropriate respecting the class as a whole.

255. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XIII. INTERSTATE AND INTRASTATE COMMERCE

256. At all material times, Biogen manufactured, marketed, promoted, distributed, and sold substantial amounts of Tecfidera and Vumerity in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

257. At all material times, Biogen transmitted funds, as well as contracts, invoices, and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Tecfidera and Vumerity and/or their AB-rated bioequivalents.

258. In furtherance of its efforts to restrain competition with respect to Tecfidera and Vumerity, Biogen employed the United States mail and interstate and international telephone lines, as well as means of interstate and international travel. Biogen's activities were within the flow of and have substantially affected interstate commerce.

259. Biogen's anticompetitive conduct has substantial intrastate effects in that, among other things, purchasers within each state were impaired in buying less expensive generic

Tecfidera within the state. The impairment of competition from generic Tecfidera directly impacts and disrupts commerce for purchases and sales within each state.

260. Biogen produces, manufactures, distributes, and sells Tecfidera and Vumerity throughout the United States through means of interstate commerce. Biogen sold and shipped substantial quantities of Tecfidera and Vumerity in a continuous and uninterrupted flow in interstate commerce to customers located throughout the United States. The PBMs placed Tecfidera and Vumerity on their formularies in interstate commerce and sold Tecfidera and Vumerity, directly and/or through their affiliated specialty pharmacies, in interstate commerce.

261. Biogen's business activities at issue in this Complaint were within the flow of, and substantially affected, interstate trade and commerce, as commerce is defined in Section 1 of the Clayton Act, 15 U.S.C. § 12(a).

XIV. MARKET POWER AND MARKET DEFINITION

262. Biogen had the ability to control the prices of fumarate and exclude relevant competitors. Direct evidence of Biogen's market power includes the following: (a) from 2013 through the present Biogen's per-unit manufacturing cost for fumarate has been less than 15% of the net price of the drug, *i.e.,* the price after adjusting for rebates and discounts; (b) Biogen never lowered the price of fumarate to the competitive level in response to pricing of other brand or generic drugs; and (c) from launch in April 2013 to June 2020, Biogen profitably raised the price of Tecfidera by approximately 79%. During that period, the Consumer Price rose by only 10.7%.

263. To the extent that Plaintiff is required to prove market power by defining a relevant product market, Plaintiff alleges that, for the purpose of evaluating the competitive effect of Biogen's conduct, the relevant product market is the market for Tecfidera, Vumerity, and their AB-rated generic equivalents (collectively, "fumarate") and narrower markets therein. At all relevant times, Biogen had market power in the fumarate market because it had the power

to raise or maintain the price of fumarate at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

264. A small but significant, non-transitory price increase in Biogen's price of fumarate did not cause a significant loss of sales. At competitive prices, Biogen's fumarate does not exhibit significant, positive, cross-elasticity of demand with respect to price with any MS drug other than AB-rated generic Tecfidera.

265. Biogen needed to control only fumarate, and no other products, in order to maintain the price of the products profitably at supracompetitive prices. Only the unimpaired market entry of a competing, AB-rated generic version of Tecfidera would render Biogen unable to profitably maintain supracompetitive prices for those products.

266. Doctors generally select MS drugs for their patients based on the clinical and pharmacological attributes of the drug and the patients' relevant characteristics, rather than principally on price. For clinical reasons, among others, physicians and patients prefer fumarate to other MS drugs for certain patients. Due to, among other reasons, its use and effectiveness in reducing MS relapses, delaying the progression of physical disability associated with MS, and slowing the development of MS-related brain lesions fumarate is significantly differentiated from all products other than AB-rated generic Tecfidera.

267. Fumarate's medical and clinical attributes significantly differentiate it from other MS drugs. Other MS drugs have different chemical compounds and formulations, and the FDA does not consider them to be interchangeable with fumarate.

268. Fumarate is the most frequently prescribed oral MS drug in the world. Most other pharmaceutical treatment options require intravenous infusions—Natalizumab (Tysabri) and Ocrelizumab (Ocrevus)—or injections—Interferon beta-1a (Avonex), Interferon beta-1b

(Betaseron), and Glatiramer acetate (Copaxone). And all of these IV infusions and injectables have much worse side-effect profiles than fumarate. These include skin reactions or infection at the infusion or injection site, fatigue, muscle weakness, flu-like symptoms, headache, fever, nausea, and joint pain.

269. Teriflunomide (Aubagio) is an orally administered MS drug, but it causes diarrhea, nausea, hair loss, and liver problems. In contrast, the most common side effects for fumarate are flushing and gastrointestinal upset. Those side effects are easily mitigated by taking the medication with food or aspirin.

270. Biogen advised its investors in April 2020 that the entry of another MS drug pill, Banner's Bafiertam, would not "significant[ly] impact" Tecfidera's sales. Bafiertam is monomethyl fumarate, which produces the same active metabolite as Tecfidera. Biogen explained that despite the chemical similarities, Bafiertam would not significantly affect Tecfidera's sales because Bafiertam "is not a directly substitutable A/B product."

271. Biogen's statement proved to be accurate. As of May 2024, Bafiertam sells only approximately 46,000 capsules per month (383 thirty-day supplies at 4 capsules per day). Less than 2% of the combined dimethyl, monomethyl, and diroximel fumarate unit sales are of Bafiertam.

272. At all relevant times, Biogen enjoyed high barriers to entry with respect to the above-defined relevant market due to patent protection, the high cost of entry and expansion, expenditures in marketing and physician detailing, and AB-rated generic substitution laws.

273. Until July 2020, Biogen's market share in the relevant market was 100%. From July 2020 through the present its dollar share of the market has exceeded 85%, and its unit share

has been as high as 95% and has always exceeded 45%. Biogen's anticompetitive conduct has shielded approximately 800,000 monthly unit sales of fumarate from generic competition.

274. The United States and its territories constitute the relevant geographic market.

275. Biogen's market power with respect to fumarate was substantial—it was monopoly power.

XV. MARKET EFFECTS AND DAMAGES TO THE CLASS

276. Biogen's anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting its fumarate products from generic competition. That conduct has caused Plaintiff and the Class to pay more than they would have paid for fumarate absent Biogen's illegal conduct.

277. Typically, generic versions of brand drugs are initially priced significantly below the corresponding brand drug to which they are AB-rated. As a result, upon generic entry, health plans and insureds rapidly substitute generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further due to competition among the generic manufacturers, and, correspondingly, the brand drug loses even more of its market share to the generic versions of the drug. This price competition enables all purchasers of the drug to: (a) purchase generic versions of a drug at substantially lower prices, and/or (b) purchase the brand drug at a reduced price. Consequently, brand manufacturers have a keen financial interest in impairing generic competition, and purchasers experience substantial cost inflation from that impairment.

278. But for Biogen's anticompetitive conduct, Plaintiff and Class members would have paid less for fumarate because, among other reasons, they would have: (a) substituted purchases of less-expensive AB-rated generic Tecfidera for their purchases of more-expensive

branded Tecfidera; (b) received lower prices for their few purchases of branded Tecfidera; (c) substituted purchases of less-expensive AB-rated generic Tecfidera for the prescriptions that Biogen switched from Tecfidera to Vumerity; (d) paid far less for their purchases of AB-rated generic Tecfidera; and (e) paid less for their few purchases of Vumerity.

279. During the Class Period, Plaintiff and other Class members purchased substantial amounts of Biogen's fumarate. As a result of Biogen's illegal conduct, Plaintiff and other Class members were compelled to pay, and did pay, artificially inflated prices for Biogen's fumarate drugs. Plaintiff and the other Class members paid prices for Biogen's fumarate that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because they: (1) were deprived of the opportunity to purchase lower-priced generic Tecfidera instead of expensive brand Tecfidera and/or brand Vumerity; (2) paid artificially inflated prices for Tecfidera and Vumerity; and (c) paid artificially inflated prices for generic Tecfidera.

280. As a consequence, Plaintiff and other Class members have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

XVI. ANTITRUST IMPACT

281. During the relevant period, Plaintiff and Class members purchased substantial amounts of fumarate drugs indirectly from Biogen and/or purchased substantial amounts of AB-rated generic Tecfidera directly from others, including from Biogen's Co-Conspirator specialty pharmacies. As a result of Biogen's illegal conduct, Plaintiff and Class members were compelled to pay, and did pay, artificially inflated prices for their fumarate requirements. Those prices were substantially greater than the prices that Plaintiff and Class members would have paid absent

Biogen's illegal conduct because they: (1) were deprived of the opportunity to purchase lower-priced generic Tecfidera instead of expensive brand Tecfidera and/or brand Vumerity; (2) paid artificially inflated prices for Tecfidera and Vumerity; and (3) paid artificially inflated prices for generic Tecfidera.

282. Overcharges at a higher level of distribution generally result in higher prices at every level below. Wholesalers and retailers passed on the inflated prices of fumarate drugs to Plaintiff and Class members, and the Co-Conspirator specialty pharmacies directly charged inflated prices to Plaintiff and Class members.

283. Biogen's anticompetitive conduct enabled it to indirectly charge health plans and insureds prices in excess of what Biogen otherwise would have been able to charge absent Biogen's anticompetitive conduct. Another purpose and effect of Biogen's anticompetitive conduct was to enable the PBM-affiliated specialty pharmacies to charge health plans and insureds prices in excess of what those pharmacies otherwise would have been able to charge.

284. The prices were inflated as a direct, foreseeable, and intended result of Biogen's anticompetitive conduct. The inflated prices that Plaintiff and Class members paid are traceable to, and the foreseeable result of, the overcharges that Biogen's conduct caused.

285. Biogen's unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure, and their injuries flow from that which makes Biogen's conduct unlawful.

XVII. COMPLIANCE WITH NOTICE AND DEMAND REQUIREMENTS

286. In accordance with the requirements of Arizona Revised Statute § 44-1415; Conn. Gen. State. § 35-37; Minn. Stat. § 325D.63; Nevada Revised Statute § 598A.210(3); Or. Rev. Stat. § 646.780(5)(b); Rhode Island General Laws § 6-36-21; and Utah Code § 76-10-3109, on or

about September 20, 2024, Plaintiff's counsel sent letters regarding this class-action complaint to the Attorneys General of Arizona, Connecticut, Minnesota, Nevada, Oregon, Rhode Island, and Utah. The letters informed the Attorneys General of the existence of this complaint, identified the relevant state antitrust provisions at issue, and enclosed a copy of this complaint.

287. On or about September 20, 2024, counsel sent demand letters to Biogen regarding this class-action complaint, which satisfy the demand-letter requirements of certain consumer-protection statutes mentioned below (e.g., Massachusetts). The demand letters identified the claimant as Plaintiff, in its individual and representative capacity; described the allegedly unfair or deceptive acts or practices that Biogen committed (i.e., its efforts to suppress competition from generic Tecfidera); described Plaintiff's and Class members' injury (increased prices for fumarate); set forth a demand for relief (treble damages, attorneys' fees, litigation costs, and other available sanctions); and requested an offer to cure within the statutorily prescribed time.

XVIII. CLAIMS FOR RELIEF

CLAIM ONE
VIOLATION OF 15 U.S.C. § 1
CONTRACT IN RESTRAINT OF TRADE

288. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

289. At all relevant times, Biogen possessed market power in the relevant market. Biogen possessed the power to raise and maintain supracompetitive prices and exclude competitors from the relevant market.

290. Biogen entered into agreements with each of the three PBMs pursuant to which it agreed to pay, and did pay, substantial kickbacks to each of them in exchange for their reciprocal agreement to disadvantage generic Tecfidera on their formularies and/or to designate generic

Tecfidera as a specialty drug. Biogen made each of the agreements with the purpose and effect of impairing generic competition to buy time for Biogen to switch the market from Tecfidera to Vumerity. When entering into the agreements, each of the three PBMs knew and understood Biogen's intent and the agreements' likely effect.

291. The purpose and effect of the payments that Biogen made to the three PBMs under the agreements was to substantially impair competition from generic Tecfidera. There is and was no legitimate, non-pretextual, procompetitive business justification for the payments that outweighs their harmful effects. Even if there were some such conceivable justification, the payments were not necessary to achieve such a purpose.

292. The agreements, individually and collectively, covered a sufficiently substantial percentage of the relevant commerce to harm competition.

293. As a direct and proximate result of Biogen's unlawful restraint of trade, Plaintiff and Class members paid artificially inflated prices for fumarate and were harmed as a result.

294. Plaintiff and Class members have been injured in their business or property by reason of Biogen's antitrust violations. These injuries are of the type that the Sherman Antitrust Act, 15 U.S.C. § 1, was designed to prevent, and flow from that which makes Biogen's conduct unlawful.

295. Plaintiff and Class members seek damages, treble damages, and injunctive relief as permitted by law for the injuries they suffered as a result of Biogen's anticompetitive conduct.

CLAIM TWO
VIOLATION OF 15 U.S.C. § 2
MONOPOLIZATION

296. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

297. At all relevant times, Biogen possessed substantial market power (i.e. monopoly power) in the relevant market. Biogen possessed the power to raise and maintain supracompetitive prices and exclude competitors from the relevant market.

298. Biogen engaged in an exclusionary, anticompetitive scheme designed to create and maintain a monopoly in the market for fumarate. Biogen's anticompetitive scheme included, cumulatively and in the alternative: (a) paying one or more of the three PBMs to disadvantage generic Tecfidera on their formularies; (b) paying one or more of the three PBMs with the purpose and effect of causing them to designate generic Tecfidera as a specialty drug; (c) making those payments knowing that the PBMs owed a fiduciary duty to their health-plan clients and that they hid some or all of the payments from their clients and funneled some or all of the payments to offshore affiliates; and (d) engaging in this conduct in order to switch the market from Tecfidera to Vumerity.

299. Through the anticompetitive scheme described above, Biogen willfully maintained and continues to maintain monopoly power in the relevant market using restrictive and exclusionary conduct, rather than by providing better products or services, and thereby injured the Plaintiff and Class members.

300. Biogen's conscious objective was and is to continue its dominance of the relevant market by and through the anticompetitive scheme described above.

301. Biogen's anticompetitive scheme harmed competition and purchasers as alleged above.

302. There are no non-pretextual procompetitive justifications for Biogen's conduct. Even if there were such a conceivable justification, the conduct's anticompetitive effects far

outweigh any conceivable justification. Further, the anticompetitive scheme was far broader than necessary to achieve any conceivable procompetitive benefit.

303. Biogen's anticompetitive scheme was the direct and proximate cause of the injuries to Plaintiff and Class members.

304. Plaintiff and the Class members have been injured in their business or property as a direct and proximate result of Biogen's anticompetitive conduct, and their injuries are the type that the Sherman Antitrust Act, 15 U.S.C. § 2, was designed to prevent, and flow from that which makes Biogen's conduct unlawful.

305. Plaintiff and Class members seek damages, treble damages, and injunctive relief as permitted by law for the injuries they suffered as a result of Biogen's anticompetitive conduct.

CLAIM THREE
VIOLATION OF 15 U.S.C. § 13(c)
COMMERCIAL BRIBERY

306. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

307. Commercial bribery violates Section 2(c) of the Robinson-Patman Act. As described in this Complaint, Biogen engaged in a commercial bribery scheme relating to the sale of fumarate drug products in the United States.

308. PBMs have, and hold themselves out as having, superior knowledge and expertise about price negotiations with brand-drug manufacturers and the use of formularies to reduce the cost of prescription drugs. Because of the PBMs' superior knowledge and expertise, health plans retain PBMs to negotiate with Biogen and other drug manufacturers on their behalf.

309. PBMs tell their health plan clients and the public that they help health plans reduce the costs associated with providing prescription drugs to plan subscribers. Health plans

rely on PBMs to control decisions about formulary inclusion and placement, trusting that the PBMs will use their skill, knowledge, and influence in the prescription drug industry to lower their clients' prescription drug costs.

310. Based on the relationship between PBMs and their health-plan clients, PBMs owe a fiduciary duty or a duty of fidelity or obligation to those clients, including to Plaintiff and Class members.

311. When Biogen negotiates with a PBM regarding the price of Tecfidera or Vumerity, Biogen knows that the PBM is negotiating on behalf of the PBM's health-plan clients who are purchasing those drugs for their plan members.

312. Biogen knowingly made payments to the PBMs and their affiliated aggregators that were conditioned on the PBMs not advantaging lower cost generic Tecfidera over Tecfidera and Vumerity on plan formularies. Biogen made those payments so that Biogen could continue charging excessive and supracompetitive prices for Tecfidera and Vumerity by limiting competition from generic Tecfidera. Biogen knew that these rebates and fees were actually commercial bribes and that the PBMs would retain some or all of the payments for themselves and would not disclose the retained portion of the payment to their clients, the plans.

313. The PBMs kept some or all of Biogen's payments for themselves. Moreover, the PBMs did not disclose to their health-plan clients that the PBMs had received payments from Biogen in exchange for impairing competition from generic Tecfidera, or that Biogen and the PBMs were impairing that competition in the service of switching the market from Tecfidera to Vumerity.

314. By accepting and keeping Biogen's payments in exchange for impairing generic Tecfidera, the PBMs violated their fiduciary duty or duty of fidelity or obligation owed to their

health-plan clients. Impairing generic Tecfidera raised their health plan clients' costs, which was the opposite of what the health plans trusted the PBMs to do for them.

315. There is no legitimate business justification for impairing generic Tecfidera. Generic Tecfidera produces the same active ingredient as Tecfidera and Vumerity, and generic Tecfidera is substantially less costly than Tecfidera and Vumerity.

316. Biogen's payments to PBMs were conditioned on disadvantaging generic Tecfidera on the PBMs' formularies and were therefore commercial bribes in violation of Section 2(c) of the Robinson-Patman Act.

317. Had Biogen not bribed the PBMs, the PBMs would have given generic Tecfidera more favorable placement on their formularies to promote the use of generic Tecfidera over the higher-cost Tecfidera and Vumerity. Favorable placement on the PBMs' formularies for generic Tecfidera would have resulted in a significant shift in sales to the lower-cost generic Tecfidera from the higher-cost Tecfidera and Vumerity.

318. Biogen's bribery scheme has corrupted what should be legitimate negotiations between PBMs and drug manufacturers to reduce the costs associated with administering prescription drug benefits. The proper role of PBMs is to use formulary placement decisions to generate competition among manufacturers of drugs with similar applications. By awarding more favorable formulary placement to the least costly drug, PBMs create incentives for drug manufacturers to become the lowest-cost provider.

319. In contrast, Biogen made payments to the PBMs with the intent of improperly influencing or corrupting the PBMs' process of awarding favorable formulary placement to low-cost products over higher-cost alternatives. Biogen used those payments to significantly impair competition from generic Tecfidera, the lowest-cost option, while promoting the use of higher-

cost Tecfidera and Vumerity. In this scheme, Biogen and the PBMs benefitted at the expense of Plaintiff and Class members.

320. Plaintiff and Class members were injured by Biogen's bribery scheme because they paid supracompetitive prices for fumarate. Plaintiff therefore has suffered substantial damages in the form of overcharges on fumarate. Plaintiff's and the Class members' injury is the type of injury that the antitrust laws were designed to prevent and flows from the anticompetitive effects that make Biogen's acts unlawful.

321. Plaintiff and Class members seek damages, treble damages, and injunctive relief as permitted by law for the injuries they suffered as a result of Biogen's anticompetitive conduct.

CLAIM FOUR
CONTRACT IN RESTRAINT OF TRADE UNDER STATE LAW

322. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

323. Biogen entered into agreements with each of the three PBMs pursuant to which it agreed to pay, and did pay, substantial kickbacks to each of them in exchange for each of their reciprocal agreement to disadvantage generic Tecfidera on their formularies and/or to designate generic Tecfidera as a specialty drug. Biogen made each of the agreements with the purpose and effect of impairing generic competition to buy time for Biogen to switch the market from Tecfidera to Vumerity. When entering into the agreements, each of the three PBMs knew and understood Biogen's intent and the agreements' likely effect.

324. The purpose and effect of Biogen's payments to the three PBMs under the agreements was to substantially impair competition from generic Tecfidera. There is and was no legitimate, non-pretextual, procompetitive business justification for the payments that outweighs

their harmful effects. Even if there were some such conceivable justification, the payments were not necessary to achieve such a purpose.

325. The agreements, individually and collectively, covered a sufficiently substantial percentage of the relevant commerce to harm competition.

326. As a direct and proximate result of Biogen's unlawful restraint of trade, Plaintiff and Class members paid artificially inflated prices for fumarate and were harmed as a result.

327. By engaging in the foregoing conduct, Biogen has violated the following state laws:

a. Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchase of fumarate in Arizona by class members and/or purchases by Arizona residents.

b. Conn. Gen. Stat. §§ 35-24, *et seq*., with respect to purchase of fumarate in Connecticut by class members and/or purchases by Connecticut residents.

c. D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchase of fumarate in the District of Columbia by class members and/or purchases by D.C. residents.

d. Fla. Stat. §§ 501.201, *et seq*., with respect to purchases in Florida by Plaintiff, members of the Class and/or purchases by Florida residents.

e. 740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchase of fumarate in Illinois by class members and/or purchases by Illinois residents.

f. Iowa Code §§ 553.1, *et seq.*, with respect to purchase of fumarate in Iowa by class members and/or purchases by Iowa residents.

g. Kan. Stat. §§ 50-101, *et seq.*, with respect to purchase of fumarate in Kansas by class members and/or purchases by Kansas residents.

h. Me. Rev. Stat. 10 §§ 1102, *et seq.*, with respect to purchase of fumarate in Maine by class members and/or purchases by Maine residents.

i. Md. Com'l Law Code Ann. §§ 11-201, *et seq.*, with respect to purchase of fumarate in Maryland by Plaintiff, class members and/or purchases by Maryland residents.

j. Mich. Comp. Laws §§ 445.771, *et seq.*, with respect to purchase of fumarate in Michigan by class members and/or purchases by Michigan residents.

k. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchase of fumarate in Minnesota by class members and/or purchases by Minnesota residents.

l. Miss. Code §§ 75-21-1, *et seq.*, with respect to purchase of fumarate in Mississippi by class members and/or purchases by Mississippi residents.

m. Neb. Code §§ 59-801, *et seq.*, with respect to purchase of fumarate in Nebraska by class members and/or purchases by Nebraska residents.

n. Nev. Rev. Stat. §§ 598A.010, *et seq.*, with respect to purchase of fumarate in Nevada by class members and/or purchases by Nevada residents.

o. N.H. Rev. Stat. §§ 356:1, *et seq.*, with respect to purchase of fumarate in New Hampshire by class members and/or purchases by New Hampshire residents.

p. N.J.S. 56:9-1, *et seq.*, with respect to purchase of fumarate in New Jersey by class members and/or purchases by New Jersey residents.

q. N.M. Stat. §§ 57-1-1, *et seq.*, with respect to purchase of fumarate in New Mexico by class members and/or purchases by New Mexico residents.

r. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchase of fumarate in North Carolina by class members and/or purchases by North Carolina residents.

s. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchase of fumarate in North Dakota by class members and/or purchases by North Dakota residents.

t. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchase of fumarate in Oregon by class members and/or purchases by Oregon residents.

u. P.R. Laws tit. 10 §§ 257, *et seq.*, with respect to purchase of fumarate in Puerto Rico by class members and/or purchases by Puerto Rico residents.

v. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchase of fumarate in Rhode Island by class members and/or purchases by Rhode Island residents.

w. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchase of fumarate in South Dakota by class members and/or purchases by South Dakota residents.

x. Tenn. Code Ann. §§ 47-25-101, *et seq*., with respect to purchases in Tennessee by members of the Class and/or by Tennessee residents.

y. Utah Code Ann. §§ 76-10-3101, *et seq.* with respect to purchase of fumarate in Utah by class members and/or purchases by Utah residents.

z. W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchase of fumarate in West Virginia by class members and/or purchases by West Virginia residents.

aa. Wis. Stat. §§ 133.01, *et seq.*, with respect to purchase of fumarate in Wisconsin by class members and/or purchases by Wisconsin residents.

328. Plaintiff and Class members have been injured in their business or property by reason of Biogen's antitrust violations. These injuries are of the type that the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Biogen's conduct unlawful.

329. Plaintiff and the Class seek damages, multiple damages, and other relief as permitted by law.

CLAIM FIVE
MONOPOLIZATION
UNDER STATE LAW

330. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

331. At all relevant times, Biogen possessed substantial market power (i.e. monopoly power) in the relevant market. Biogen possessed the power to raise and maintain supracompetitive prices and exclude competitors from the relevant market.

332. Biogen engaged in an exclusionary, anticompetitive scheme designed to create and maintain a monopoly in the market for fumarate. Biogen's anticompetitive scheme included, cumulatively and in the alternative: (a) paying one or more of the three PBMs to disadvantage generic Tecfidera on their formularies and/or to designate generic Tecfidera as a specialty drug; and (b) switching the market from Tecfidera to Vumerity.

333. Through the anticompetitive scheme described above, Biogen willfully maintained and continues to maintain monopoly power in the relevant market using restrictive and exclusionary conduct, rather than by providing better products or services, and thereby injured the Plaintiff and Class members.

334. Biogen's conscious objective was and is to continue its dominance of the relevant market by and through the anticompetitive scheme described above.

335. Biogen's anticompetitive scheme harmed competition and purchasers as alleged above.

336. There are no non-pretextual procompetitive justifications for Biogen's conduct. Even if there were such a conceivable justification, the conduct's anticompetitive effects far outweigh any conceivable justification. Further, the anticompetitive scheme was far broader than necessary to achieve any conceivable procompetitive benefit.

337. Biogen's anticompetitive scheme was the direct and proximate cause of the injuries to Plaintiff and Class members.

338. Plaintiff and the Class members have been injured in their business or property as a direct and proximate result of Biogen's anticompetitive conduct, and their injuries are the statutes were designed to prevent, and flow from that which makes Biogen's conduct unlawful.

339. Plaintiff and the Class members seek damages and treble damages as permitted by law for the injuries they suffered as a result of the Biogen's anticompetitive conduct.

340. By engaging in the foregoing conduct, Biogen has violated the following state laws:

a. Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchase of fumarate in Arizona by class members and/or purchases by Arizona residents.

b. Conn. Gen. Stat. §§ 35-24, *et seq*., with respect to purchase of fumarate in Connecticut by class members and/or purchases by Connecticut residents.

c. D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchase of fumarate in the District of Columbia by class members and/or purchases by D.C. residents.

d. Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by Plaintiff, members of the Class and/or purchases by Florida residents.

e. 740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchase of fumarate in Illinois by class members and/or purchases by Illinois residents.

f. Iowa Code §§ 553.1, *et seq.*, with respect to purchase of fumarate in Iowa by class members and/or purchases by Iowa residents.

g. Kan. Stat. §§ 50-101, *et seq.*, with respect to purchase of fumarate in Kansas by class members and/or purchases by Kansas residents.

h. Me. Rev. Stat. 10 §§ 1102, *et seq.*, with respect to purchase of fumarate in Maine by class members and/or purchases by Maine residents.

i. Md. Com'l Law Code Ann. §§ 11-201, *et seq.*, with respect to purchase of fumarate in Maryland by Plaintiff, class members and/or purchases by Maryland residents.

j. Mich. Comp. Laws §§ 445.771, *et seq.*, with respect to purchase of fumarate in Michigan by class members and/or purchases by Michigan residents.

k. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchase of fumarate in Minnesota by class members and/or purchases by Minnesota residents.

l. Miss. Code §§ 75-21-1, *et seq.*, with respect to purchase of fumarate in Mississippi by class members and/or purchases by Mississippi residents.

m. Neb. Code §§ 59-801, *et seq.*, with respect to purchase of fumarate in Nebraska by class members and/or purchases by Nebraska residents.

n. Nev. Rev. Stat. §§ 598A.010, *et seq.*, with respect to purchase of fumarate in Nevada by class members and/or purchases by Nevada residents.

o. N.H. Rev. Stat. §§ 356:1, *et seq.*, with respect to purchase of fumarate in New Hampshire by class members and/or purchases by New Hampshire residents.

p. N.M. Stat. §§ 57-1-1, *et seq.*, with respect to purchase of fumarate in New Mexico by class members and/or purchases by New Mexico residents.

q. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchase of fumarate in North Carolina by class members and/or purchases by North Carolina residents.

r. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchase of fumarate in North Dakota by class members and/or purchases by North Dakota residents.

s. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchase of fumarate in Oregon by class members and/or purchases by Oregon residents.

t. P.R. Laws tit. 10 §§ 257, *et seq.*, with respect to purchase of fumarate in Puerto Rico by class members and/or purchases by Puerto Rico residents.

u. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchase of fumarate in Rhode Island by class members and/or purchases by Rhode Island residents.

v. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchase of fumarate in South Dakota by class members and/or purchases by South Dakota residents.

w. Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the Class and/or purchases by Tennessee residents.

x. Utah Code Ann. §§ 76-10-3101, *et seq.* with respect to purchase of fumarate in Utah by class members and/or purchases by Utah residents.

y. W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchase of fumarate in West Virginia by class members and/or purchases by West Virginia residents.

z. Wis. Stat. §§ 133.01, *et seq.*, with respect to purchase of fumarate in Wisconsin by class members and/or purchases by Wisconsin residents.

341. Plaintiff and Class members have been injured in their business or property by reason of Biogen's antitrust violations. These injuries are of the type that the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Biogen's conduct unlawful.

342. Plaintiff and the Class seek damages, multiple damages, and other relief as permitted by law.

CLAIM SIX
UNFAIR OR UNCONSCIONABLE ACTS AND PRACTICES UNDER STATE LAW

343. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

344. Biogen engaged in unfair methods of competition, unfair and unconscionable acts or practices, or deceptive acts or practices, in order to wrongfully restrain trade in the fumarate market, and in violation of the state consumer-protection statutes identified below.

345. As noted in detail above, these practices include paying the three PBMs to disadvantage generic Tecfidera on their formularies and to designate generic Tecfidera as a specialty drug, all in the service of effecting a market switch from Tecfidera to Vumerity and impairing competition from generic Tecfidera.

346. As a proximate result of Biogen's unfair, unconscionable, and deceptive conduct, Plaintiff and the Class were deprived of a market in which: (1) the prescription base available for automatic generic substitution is determined by unrestrained competition; (2) they receive the honest services of PBMs, untainted by kickbacks for covering higher-priced branded drugs rather than generics; (3) generic drug manufacturers have unimpaired access to the most cost efficient means of distribution; and (4) follow-on branded products must compete on the merits, unaided by kickbacks that enable and facilitate a market switch designed to impair generic competition.

347. There was and is a gross disparity between the price that Plaintiff and Class members actually paid for fumarate and the price that they would have paid absent Biogen's conduct. Much more affordable generic Tecfidera would have been able to compete on the merits, and prices for fumarate would have been far lower, but for Biogen's unfair,

unconscionable, and deceptive conduct. This injury is of the type the state consumer-protection statutes were designed to prevent, and it directly results from Biogen's unlawful conduct.

348. To the extent deception is required under any of the state laws below, but for Biogen's deceptive acts, fumarate prices would have been lower. For example, Biogen aggressively and falsely marketed Vumerity as superior to Tecfidera; paid the PBMs to falsely designate generic Tecfidera as a specialty drug; and paid fees to the PBMs knowing that the PBMs hid the fees from Plaintiff and Class members and funneled the fees to the PBMs' offshore affiliates. Biogen's misstatements resulted in overcharges to Plaintiff and the Class, even if considered independently of the rest of Biogen's unfair business practices (e.g., its agreements with PBMs to disadvantage generic Tecfidera on their formularies).

349. The gravity of harm from Biogen's wrongful conduct significantly outweighs any conceivable utility from that conduct. Plaintiff and the Class members could not have reasonably avoided injury from Biogen's wrongful conduct.

350. By engaging in such conduct, Biogen violated the following consumer-protection laws:

***California*:**

351. Section 17200 *et seq.* of the California Business and Professional Code (the "UCL") prohibits any "unlawful, unfair, or fraudulent act or practice[]."

352. Biogen violated the UCL by (among other things) engaging in its scheme to suppress the availability of generic Tecfidera, which is described above, and which included, among other things, the unlawful agreements with the PBMs and using those agreements to switch the market from Tecfidera to Vumerity.

353. Biogen violated the UCL's "unlawful" prong insofar as its conduct also violated federal antitrust law, as well as California's antitrust law (CA BUS & PROF § 16720).

354. Biogen's conduct also constitutes unfair or unconscionable acts or practices under the UCL, regardless of whether or not that conduct violates state or federal antitrust laws.

355. Biogen's conduct was intentional, i.e., it entered into exclusionary agreements, and falsely described generic Tecfidera, in order to suppress generic competition in the fumarate market, and with the express purpose of misleading members of the Class.

356. Biogen's conduct did deceive and would have deceived reasonable persons, including the Class.

357. Class members purchased fumarate within California during the Class Period.

358. Biogen's conduct was the proximate cause of injuries to the Class, namely in the form of overcharges on fumarate. For example, had Biogen competed on the merits instead of unlawfully maintaining its monopoly in fumarate, then generic Tecfidera would have been more readily available to the Class, and they would have substituted lower-priced generic dimethyl fumarate for the higher-priced brand-name Tecfidera and Vumerity.

359. Because fumarate is purchased on an ongoing basis, to treat MS, there is a high probability that Class members will suffer injury in the future, as a result of Biogen's conduct.

360. This claim is instituted pursuant to sections 17203 and 17204 of the California Business and Professions Code, to obtain restitution from Biogen for acts that violated the UCL, as described above.

361. The Class is entitled to full restitution and disgorgement of all revenues, earnings, profits, compensation, and benefits that Biogen obtained as a result of its efforts to suppress generic Tecfidera. The Class is also entitled to all other appropriate relief under the UCL.

***Florida*:**

362. The Florida Deceptive and Unfair Trade Practices Act (the "FDUTPA") prohibits "unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." FLA STAT. § 501.204(1).

363. Biogen engaged in unfair methods of competition by (among other things) engaging in its scheme to suppress the availability of generic Tecfidera, which is described above, and which included, among other things, the unlawful agreements with the PBMs and using those agreements to switch the market from Tecfidera to Vumerity.

364. Biogen's conduct was intentional, i.e., it entered into exclusionary agreements, and falsely described generic Tecfidera, in order to suppress generic competition in the fumarate market, and with the express purpose of misleading members of the Class.

365. Biogen's conduct did deceive and would have deceived reasonable persons, including the Class.

366. Biogen's conduct was the proximate cause of injuries to the Class, namely in the form of overcharges on fumarate. For example, had Biogen competed on the merits instead of unlawfully maintaining its monopoly in fumarate, then generic Tecfidera would have been more readily available to the Class, and they would have substituted lower-priced generic dimethyl fumarate for the higher-priced brand-name Tecfidera and Vumerity.

367. Because fumarate is purchased on an ongoing basis to treat MS, there is a high probability that Class members will suffer injury in the future, as a result of Biogen's conduct.

368. During the Class Period, Plaintiff and Class members purchased fumarate in Florida.

369. In light of the above, members of the Class are entitled to seek all forms of relief under the FDUTPA, including injunctive relief pursuant to Florida Statute § 501.208, as well as a declaratory judgment, actual damages, punitive damages (to the extent available), reasonable attorneys' fees, and costs. *See* FLA. STAT. § 501.211.

***Hawaii*:**

370. Hawaii's Unfair and Deceptive Acts or Trade Practices Act prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." HAW. REV. STAT. § 480-2.

371. Hawaii's Uniform Deceptive Trade Practices Act prohibits defendants from (among other things) "[d]isparag[ing] the goods, services, or business of another by false or misleading representation of fact." HAW. REV. STAT. § 481A-3(8); *see also id.* at (5), (7), (12).

372. Biogen's anticompetitive efforts to suppress generic Tecfidera, which are described above, constituted an unfair method of competition, or an unfair trade practice, under Hawaii's Unfair and Deceptive Acts or Trade Practices Act.

373. Biogen's false or misleading statements regarding fumarate (among other things), which are also described above, constituted disparagement, false advertising, etc., under Hawaii's Deceptive Trade Practices Act.

374. Biogen's conduct was intentional, i.e., it entered into exclusionary agreements and falsely described generic Tecfidera in order to suppress generic competition in the fumarate market, and with the express purpose of misleading members of the Class.

375. Biogen's conduct did deceive and would have deceived reasonable persons, including the Class.

376. Class members purchased fumarate within Hawaii during the Class Period.

377. Biogen's conduct was the proximate cause of injuries to the Class, namely in the form of overcharges on fumarate. For example, had Biogen competed on the merits instead of unlawfully maintaining its monopoly in fumarate, then generic Tecfidera would have been more readily available to the Class, and they would have substituted lower-priced generic dimethyl fumarate for the higher-priced brand-name Tecfidera and Vumerity.

378. In light of the above, members of the Class are entitled to seek all available relief under Hawaii's consumer-protection laws, including actual damages, treble damages, punitive damages (to the extent available), injunctive relief, attorneys' fees, and costs.

***Idaho*:**

379. The Idaho Consumer Protection Act (the "ICPA") prohibits "unfair methods of competition and unfair or deceptive acts and practices in the conduct of trade or commerce," IDAHO CODE §§ 48-601, which includes, among other things, "[d]isparaging the goods . . . of another by false or misleading representation of fact," IDAHO CODE § 48-603(8); *see also id.* at (7), (17), (18). Idaho also prohibits "any unconscionable method, act or practice in the conduct of any trade or commerce." IDAHO CODE § 48-603C.

380. Biogen's conduct was intentional, i.e., it entered into exclusionary agreements and falsely described generic Tecfidera in order to suppress generic competition in the fumarate market, and with the express purpose of misleading members of the Class.

381. Biogen's conduct did deceive and would have deceived reasonable persons, including the Class.

382. Biogen's conduct was the proximate cause of injuries to the Class, namely in the form of overcharges on fumarate. For example, had Biogen competed on the merits instead of unlawfully maintaining its monopoly in fumarate, then generic Tecfidera would have been more

readily available to the Class, and they would have substituted lower-priced generic dimethyl fumarate for the higher-priced brand-name Tecfidera and Vumerity.

383. Biogen's alleged conduct—which forced sufferers of MS to overpay for their medication—would outrage or offend the public conscious.

384. During the Class Period, Class members purchased fumarate in Idaho.

385. Because fumarate is purchased on an ongoing basis to treat MS, there is a high probability that Class members will suffer injury in the future, as a result of Biogen's conduct.

386. In light of the above, The Class is entitled to actual damages, along with any other form of relief that the Court deems proper under the ICPA, including actual damages, statutory damages, punitive damages, attorneys' fees, costs, and injunctive relief. *See* IDAHO CODE § 48-608.

***Massachusetts*:**

387. The Massachusetts Consumer Protection Act (the "MaCPA") prohibits "unfair or deceptive act or practice." MASS. GEN. LAWS ch. 93A, § 9(2).

388. Biogen's anticompetitive scheme to suppress generic Tecfidera, which is described above, constituted an unfair act or practice under the MaCPA.

389. Biogen's efforts to falsely designate generic dimethyl fumarate (among other things), as described above, constituted a deceptive act or practice under the MaCPA.

390. Biogen's conduct was intentional, i.e., it entered into exclusionary agreements, and falsely described generic Tecfidera, in order to suppress generic competition, and with the express purpose of misleading Class members.

391. Biogen's conduct did deceive and would have deceived reasonable persons, including the Class.

392. Biogen's conduct was the proximate cause of injuries to the Class, namely in the form of overcharges on fumarate. For example, had Biogen competed on the merits instead of unlawfully maintaining its monopoly in fumarate, then generic Tecfidera would have been more readily available to the Class, and they would have substituted lower-priced generic dimethyl fumarate for the higher-priced brand-name Tecfidera and Vumerity.

393. During the Class Period, members of the Class purchased fumarate within the Commonwealth of Massachusetts.

394. Because fumarate is purchased on an ongoing basis to treat MS, there is a high probability that Class members will suffer injury in the future, as a result of Biogen's conduct.

395. In light of the above, the Class is seeking all forms of relief under the MaCPA, including actual damages, treble damages, punitive damages (to the extent available), reasonable attorney's fees, costs, and injunctive relief. *See* MASS. GEN. LAWS ch. 93A § 9(3A).

***New York*:**

396. New York's General Business Law prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce." N.Y. GEN. BUS. LAW § 349(a), (g); N.Y. GEN. BUS. LAW § 350 (prohibiting false advertising).

397. Biogen's efforts to inhibit generic Tecfidera, which are described above (e.g., its exclusionary agreements with PBMs and its falsely designating generic dimethyl fumarate, among other things), constitute deceptive acts or practices under the GBL.

398. Biogen's conduct was intentional, i.e., it entered into exclusionary agreements, and falsely described generic Tecfidera, in order to suppress generic competition in the fumarate market, and with the express purpose of misleading members of the Class.

399. Biogen's conduct did deceive and would have deceived reasonable persons, including the Class.

400. Biogen's conduct was the proximate cause of injuries to the Class, namely in the form of overcharges on fumarate. For example, had Biogen competed on the merits instead of unlawfully maintaining its monopoly in fumarate, then generic Tecfidera would have been more readily available to the Class, and they would have substituted lower-priced generic dimethyl fumarate for the higher-priced brand-name Tecfidera and Vumerity.

401. During the Class Period, members of the Class purchased fumarate in New York.

402. Because fumarate is purchased on an ongoing basis to treat MS, there is a high probability that Class members will suffer injury in the future, as a result of Biogen's conduct.

403. In light of the above, the Class is entitled to all available forms of relief under the GBL, including actual damages, treble damages, statutory damages, punitive damages (to the extent available), reasonable attorneys', costs, and injunctive relief.

***Vermont*:**

404. Title 9 of the Vermont Statutes prohibits "[u]nfair methods of competition in commerce and unfair or deceptive acts or practices in commerce." VT. STAT. tit. 9, § 2453.

405. Biogen's efforts to inhibit generic Tecfidera, which are described above (e.g., its exclusionary agreements with PBMs and its falsely designating generic dimethyl fumarate, among other things), constitute unfair practices under § 2453. Biogen also engaged in deceptive practices under the statute by (among other thing) falsely designating generic Tecfidera.

406. Biogen's conduct was intentional, i.e., it entered into exclusionary agreements, and falsely described generic Tecfidera, in order to suppress generic competition in the fumarate market, and with the express purpose of misleading members of the Class.

407. Biogen's conduct did deceive and would have deceived reasonable persons, including the Class.

408. Biogen's conduct was the proximate cause of injuries to Plaintiff and the Class, namely in the form of overcharges on fumarate. For example, had Biogen competed on the merits instead of unlawfully maintaining its monopoly in fumarate, then generic Tecfidera would have been more readily available to the Class, and they would have substituted lower-priced generic dimethyl fumarate for the higher-priced brand-name Tecfidera and Vumerity.

409. During the Class Period, members of the Class purchased fumarate in Vermont.

410. Because fumarate is purchased on an ongoing basis to treat MS, there is a high probability that Class members will suffer injury in the future, as a result of Biogen's conduct.

411. In light of the above, the Class is entitled to all available forms of relief under Vermont's consumer-protection statute, including actual damages, punitive damages (to the extent available), attorneys' fees, costs, and injunctive relief.

XIX. DEMAND FOR JUDGMENT

412. WHEREFORE, Plaintiff, on behalf of itself and the Class, demands judgment in its favor and respectfully requests that the Court:

a. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a), 23 (b)(2) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class and declare the Plaintiff a representative of the Class;

b. Declare that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act, of Section 2(c) of the Robinson-Patman Act, and of the other statutes set forth above;

c. Enter judgment against Biogen in favor of Plaintiff and the Class;

d. Grant Plaintiff and the Class equitable relief in the nature of disgorgement, restitution, the creation of a constructive trust, mandatory licenses, and other injunctive relief, to remedy Biogen's anticompetitive conduct;

e. Award the Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

f. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

g. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by Biogen's unlawful conduct, and as the Court deems just.

XX. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff on behalf of itself and the proposed Class demands a trial by jury on all issues so triable.

Dated: September 20, 2024

By: */s/ Carol V. Gilden*

Carol V. Gilden
ARDC No. 6185530
COHEN MILSTEIN SELLERS & TOLL PLLC
190 South LaSalle Street
Suite 1705
Chicago, IL 60603
Tel: (312) 357-0370
Email: cgilden@cohenmilstein.com

Sharon K. Robertson
COHEN MILSTEIN SELLERS & TOLL PLLC
88 Pine Street, 14th Floor
New York, NY 10005
Tel: (212) 838-7797
Email: srobertson@cohenmilstein.com

Attorneys for Plaintiff, the Mayor and City Council of Baltimore, and the Proposed Class